In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-1299V

Filed: October 16, 2024

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CARRIE FERGUSON,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

* *

Renée Gentry, Vaccine Injury Clinic, George Washington Univ. Law School, Washington, DC, for Petitioner;
Katherine Esposito, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION DENYING ENTITLEMENT[1]

Shah, Special Master:

On September 21, 2017, Carrie Ferguson ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 *et seq*.[2] (the "Vaccine Act" or "Program"). Petitioner initially alleged that she developed the Vaccine Injury Table ("Table")[3] injuries of shoulder injury related to vaccine administration, anaphylaxis,

[1] Because this Decision contains a reasoned explanation for the action in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. For ease, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

[3] The Vaccine Injury Table is at 42 C.F.R. § 100.3.

vasovagal syncope, and Guillain-Barré syndrome ("GBS"), from pneumococcal[4] and influenza ("flu") vaccines she received on September 22, 2014. Pet. at 1-2 (ECF No. 1). She further alleged that these vaccines caused-in-fact the following injuries:

> [P]ost-vaccination encephalopathy; post-vaccination autoimmune encephalopathy; resolved VI nerve palsy; post-vaccination left shoulder pain and swelling; paresthesia, and muscle weakness; bilateral arm dysesthesias, distal right extremity pain, right upper extremity tremor, numbness of hands; cognitive dysfunction with severe decreased recent memory; dysgraphia secondary to right hand weakness; progressive loss of dexterity in right hand/significantly weakened grip; recent radiculitis in the right deltoid to the elbow; right hand treatment/atrophy; decreased physical endurance of the right upper extremity and right hand; weakness of right brachioradialis muscle on supination/weakness in supination-pronation; weakness of the left [arm]; loss of function with decreased ability to write (dysgraphia) and perform activities of daily living (e.g. cooking, writing, dressing, helping children, penmanship, etc.)/fatigues easily; pain in right forearm; decreased short-term memory (also noticed by friends and family); increased anxiety; frequent absence spells; fever; loss of consciousness; prolonged immobility; ascending paralysis intubated and placed on life support; fluid and swelling on spine which was affecting critical body functions, causing extreme pain and limiting her ability to control her limbs; reduced auditory function; ears felt plugged; frequent tinnitus; abnormal brain function/activity that affected both sides of plaintiff's cognitive abilities (e.g. processing, emotional state and memory) and motor skills (e.g. speech, movement, physical sensations, etc.); mental and emotional pain and suffering (exacerbated by the longevity and persistence of the symptoms and the lack of treatment options); trouble swallowing; muscular atrophy; joint swelling; swelling between skeletal discs; and possibly permanent hearing loss.

Id. at 2-3.

In an amended petition filed April 20, 2022, Petitioner narrowed the scope of her allegations, claiming that her vaccinations caused-in-fact a "Type III hypersensitivity reaction with systemic inflammation, [which] cause[d] [her] to develop a secondary intracranial hypertension." Am. Pet. at 1 (ECF No. 63).

Upon review of the evidence in this case, and although I am sympathetic to her ordeal, I find that Petitioner has not established by preponderant evidence that the vaccines she received caused a cognizable injury. This case is accordingly dismissed.

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[4] There are two different types of pneumococcal vaccines: the conjugate vaccine and the polysaccharide vaccine. *Cielencki v. Sec'y of Health & Hum. Servs.*, No. 15-632V, 2015 WL 10767150, *3 (Fed. Cl. Spec. Mstr. Dec. 22, 2015). The Program only covers alleged injuries caused by pneumococcal conjugate vaccines. *See* 42 C.F.R. § 100.3(a). The Petition alleged that Petitioner received a pneumococcal conjugate vaccine. Pet. at 2. The vaccination record, however, indicates that she received the Pneumovax 23 vaccine, which is a polysaccharide vaccine not covered by the Program. *See* Ex. 2 at 2; *Cielencki*, 2015 WL 10767150, at *3.

I. Procedural History

Petitioner filed an affidavit and medical records on November 5, 2018, along with a Statement of Completion. ECF Nos. 20-24. On February 21, 2019, Respondent filed a Rule 4(c) Report asserting that the case was not appropriate for compensation. ECF No. 26.

On April 6, 2020, Petitioner filed an expert report from Carlo Tornatore, M.D. Ex. 30. Respondent filed an expert report from Brian Callaghan, M.D., on December 7, 2020. Ex. A. Petitioner filed a second report from Dr. Tornatore on April 9, 2021, and Respondent filed a second expert report from Dr. Callaghan on July 22, 2021. Exs. 34, B. Petitioner filed a third expert report from Dr. Tornatore on November 22, 2021. Ex. 38. On November 30, 2021, former Special Master Katherine E. Oler issued an order with additional questions for Dr. Callaghan. ECF No. 52. On January 31, 2022, Respondent filed a third report from Dr. Callaghan. Ex. C.

On February 1, 2022, former Special Master Oler issued an order with additional questions for Dr. Tornatore. ECF No. 56. On April 20, 2022, Petitioner filed a fourth report from Dr. Tornatore. Ex. 46. The same day, she filed the amended petition. ECF No. 63.

On August 16, 2022, Respondent filed an expert report from Andrew MacGinnitie, M.D., Ph.D. Ex. E. On October 17, 2022, Petitioner stated that she did not wish to file another responsive expert report and requested a briefing schedule for a ruling on the record. ECF No. 66.

On January 31, 2023, Petitioner filed a motion for a ruling on the record ("Motion"). ECF No. 67. Respondent filed a response to the Motion on March 31, 2023 ("Response"). ECF No. 68. Petitioner filed a reply brief on April 7, 2023 ("Reply"). ECF No. 69. On April 17, 2023, the parties filed a joint status report indicating their satisfaction that the record was complete. ECF No. 70.

This matter is now ripe for adjudication.

II. Fact Evidence

A. Petitioner's Affidavit

In an affidavit signed September 20, 2017, Petitioner recalled that on September 22, 2014, she was picking up a prescription for a scratch on her cornea when the pharmacy technician suggested she get flu and pneumonia vaccinations. Ex. 28 at 1. She received both vaccinations in her left arm. *Id.* "[V]ery shortly" after vaccination, she started experiencing flu-like symptoms, including lightheadedness, aches, labored breathing, queasiness, and blurry vision. *Id.*

Petitioner continued to feel worse, stating her arm felt like it had been "repeatedly slammed in a car door," with sharp, stabbing pain. Ex. 28 at 1. Eventually, she was unable to move her arm. *Id.* She ended up falling asleep while reading her son a story. *Id.* When she awakened the next day, she called Rite Aid and was advised to go to the hospital, so her uncle took her to the

emergency room ("ER"). *Id.* She recalled being so weak that her uncle had to dress her and "drag" her to the car. *Id.*

While at the hospital, Petitioner was "in a state of paralysis," drooling on herself and unable to speak. Ex. 28 at 1. At some point, she was intubated and underwent many tests. *Id.* at 1-2. She could recall the pain and discomfort associated with the spinal tap. *Id.* at 2.

Petitioner recalled her recovery as being difficult. Ex. 28 at 2. She would sleep throughout the day, and it took her days to regain the ability to walk after returning home. *Id.* She developed a tremor in her right hand and arm. *Id.* Her "neurologist revealed that it was the inflammation and swelling of [her] brain that had caused these issues." *Id.* It took a few weeks for her to resume her normal activities. *Id.*

In June or July 2015, Petitioner had an ovarian cyst burst, which caused great pain and possible loss of consciousness. Ex. 28 at 2. She could not speak or move her limbs, and her neighbor had to help her into a car to get to the ER. *Id.* She had another spinal tap, and immediately felt relief and was able to walk again. *Id.* at 3.

After six to seven weeks, Petitioner's symptoms of "muscle irregularities," spasms, and general pain returned. Ex. 28 at 3. She also began having trouble completing sentences and started slurring her words. *Id.* Her neuropsychologist told her she had irregular brain activity. *Id.* She experienced improvement after a third spinal tap. *Id.*

Petitioner's remaining symptoms include hearing difficulties, overall weakness, numbness in her right hand, short-term memory issues, fatigue, headaches, anxiety, nervousness, "loss of ability to control emotion around certain situations," and difficulty with mental math. Ex. 28 at 3. Her symptoms are different daily. *Id.* She eats an anti-inflammatory diet and is taking vitamin and fish oil supplements. *Id.* She has also undergone neuro-feedback therapy. *Id.* at 4.

B. Medical Records

Petitioner was thirty-two years old at the time of vaccination. Her prior medical history included seasonal and non-seasonal allergies, right shoulder and hand numbness in 2011, hernia repair in 2012, vocal cord problems in 2012, dyspnea (shortness of breath) in 2012, globus sensation[5] in 2012, and lower back pain in 2014. *See generally* Exs. 4, 6, 17, 21, 29.

On September 9, 2014, Petitioner presented to the office of her allergist, Duane Gels, M.D., complaining of itchy, watery eyes, rhinorrhea, occasional postnasal drainage, and occasional sinus pressure without significant congestion. Ex. 4 at 2. She was diagnosed with allergic and nonallergic rhinitis and prescribed Flonase, Patanase, and Pataday. *Id.*

[5] Also known as globus pharynges, which is an uncomfortable feeling of having a lump in the throat when none is there; it may be psychogenic or caused by some disorder of the esophagus or nearby cervical structures. DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=79000 (last visited October 16, 2024) ("DORLAND'S").

On September 22, 2014, Petitioner was administered the flu and Pneumovax 23 vaccines.[6] Ex. 2 at 2.

The following day, September 23, 2014, Petitioner presented to the Anne Arundel Medical Center ("AAMC") ER with complaints of fever, severe generalized headache, malaise, and left arm pain after receiving the flu and pneumonia vaccines the previous day. Ex. 29 at 131-32. She claimed that she "[s]tarted feeling bad last night, worse today." *Id.* at 132. She said she was not able to move "at all." *Id.* at 134. She stated: "I don't want to do anything" and "I just can't move." *Id.* at 132. She had a fever of 102.7 degrees. *Id.* at 133. Although she had a "sickly appearance," she was alert and oriented. *Id.*

In the ER, Petitioner was uncooperative, had absent patellar reflexes, did not withdraw her legs to painful stimulation, and appeared to have inadequate respiratory effort with drooling. Ex. 29 at 131-34, 144. She was intubated in the ER for possible GBS but became agitated after the sedation wore off. *Id.* at 137. She was moving all four extremities and responding to questions, so she was extubated in the ICU. *Id*. She was found to have an elevated white blood cell ("WBC") count, erythrocyte sedimentation rate ("ESR"), and C-reactive protein ("CRP") level. *Id.* at 134-35, 140.

That same day, critical care physician Ira Weinstein, M.D., consulted on Petitioner's case. Ex. 29 at 144. He noted that Petitioner's initial presentation was considered to be "psychogenic in origin." *Id.* Petitioner was admitted for a further medical workup and a psychiatric evaluation. *Id.*

On September 24, 2014, Petitioner was seen by neurologist Alexander Katcheves, M.D. Ex. 29 at 146. Dr. Katcheves noted Petitioner's receipt of the vaccines the day before. *Id.* He commented that she was lethargic but awakened to voice briefly and was able to follow commands. *Id.* at 146-47. She was oriented to year, place, and self, and her reflexes were 1+ and equal bilaterally in all four extremities. *Id.* at 148. Dr. Katcheves's impression was that her presentation was likely caused by a systemic infectious process. *Id.* He felt that her intact reflexes and "acute onset" of symptoms made a diagnosis of GBS unlikely. *Id.* He recommended screening for infections, reversible causes of delirium, and electrolyte abnormalities. *Id.* He also recommended a brain MRI if Petitioner did not start "interacting more." *Id.*

The same day, Petitioner was also seen by infectious disease specialist Ellen Yang, M.D. Ex. 29 at 149. Petitioner reported receiving the flu and Pneumovax vaccinations and developing a sore left arm, followed by fever and weakness the next day. *Id.* She said that she had previously received the FluMist, and that "[t]his may have been her first or second year for the influenza injection."[7] *Id.* At the time of the consultation, she seemed lethargic and reported a headache. *Id.*

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[6] The vaccination record indicates that both vaccinations were given in Petitioner's right arm. Ex. 2 at 2. She claims, however, that they were actually given in her left arm; that is what she reported to the treating infectious disease physician in the hospital. *See* Motion at 2; Ex. 29 at 149.

[7] There is no vaccination record before me documenting that Petitioner received any formulation of flu vaccination prior to the subject vaccination.

She could answer questions but would only say a few words. *Id.* An exam revealed mild redness and swelling of the left arm. *Id.* at 150. Dr. Yang stated that she was "not really sure what the etiology of [Petitioner's] weakness [was]." *Id.* She ordered a lumbar puncture ("LP") and an MRI of the brain to rule out meningitis and encephalitis. *Id.* She also raised the possibility that Petitioner was suffering from serum sickness from the vaccinations or from Macrobid,[8] or, less likely, a viral illness. *Id.* at 150, 159. A brain MRI was performed later that day, with negative results. *Id.* at 194-95.

Also on September 24, 2014, Petitioner had an LP. Ex. 29 at 153. Petitioner's positioning during the procedure was not documented. The opening pressure of the cerebrospinal fluid ("CSF") was elevated. *Id.* A culture of the CSF was not consistent with meningitis, and a test for Lyme disease was negative. *Id.* at 139-40.

Petitioner underwent a psychiatric evaluation with Vladmir Demidov, M.D., on September 25, 2014. Ex. 29 at 151. At the time, her chief complaint was a headache after her LP. *Id.* at 152. She reported no past psychiatric history. *Id.* Her exam was normal. *Id.* Dr. Demidov could not establish an appropriate psychiatric diagnosis. *Id.* at 153. He noted that the possibility of GBS or serum sickness was a "very interesting thought to entertain," but Petitioner did "not have [the] full set of symptoms" of those conditions. *Id.* He determined Petitioner's presentation was not related to any type of stress response or delirium and that he did not need to be involved in her treatment. *Id*.

On September 26, 2014, Dr. Yang wrote that Petitioner had returned to her baseline except for complaints of a headache. Ex. 29 at 173. She noted that there was no suspicion of a bacterial infection, and she again questioned whether Petitioner might be suffering from serum sickness. *Id*. She commented that there was "[n]o neurologic explanation for what happened to [her] in the ER except exaggerated psychological response to her illness. Seen by psychiatrist who [felt] that [Petitioner had] no psychiatric illness." *Id.* That day, Petitioner was discharged from AAMC, with final diagnoses of fever, headache, "likely serum sickness after receiving vaccinations," a post-LP headache, and hemorrhoids. *Id.* at 139.

On September 30, 2014, Petitioner called her allergist, Dr. Gels, to ask whether she could still receive allergy shots given her reaction to the vaccines, which she characterized as paralysis due to "GBS." Ex. 4 at 21. Dr. Gels stated that the allergy shots were not contraindicated. *Id*. He also noted that he had spoken with Dr. Yang, who clarified that Petitioner did not have GBS but was instead "signed out as serum sickness." *Id*.

Petitioner had a post-hospitalization visit with her primary care provider ("PCP"), Jack Lichtenstein, M.D., on October 1, 2014. Ex. 17 at 14. Dr. Lichtenstein commented that Petitioner had experienced a "probable" seizure with postictal paralysis, though that diagnosis was not recorded anywhere in the hospital records. *Id.* at 14-15. A review of systems ("ROS")

[8] Macrobid is a trade name for nitrofurantoin, which is used in the treatment of urinary tract infections. DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=29213&searchterm=Macrobid (last visited October 16, 2024). On September 25, 2014, Dr. Yang noted that Petitioner had been prescribed Macrobid several weeks earlier, which ruled it out as a cause of Petitioner's symptoms. Ex. 29 at 165.

was negative for headache, decrease in cognitive skills, paralysis, or loss of consciousness. *Id.* at 15. On exam, Dr. Lichtenstein observed a right arm tremor. *Id*. He referred Petitioner for a neurology consult and additional lab work. *Id*.

On October 8, 2014, Petitioner saw neurologist Nicholas Capozzoli, M.D., for "GBS," muscle weakness, and paresthesias. Ex. 22 at 19. A ROS showed that Petitioner had residual paresthesias of the arms and legs that were improving. *Id.* at 20. She reported no vision problems. *Id.* Her neurological exam, including assessment of the cranial nerves, was normal. *Id.* Dr. Capozzoli remarked that Petitioner "had a catastrophic reaction possibly to a flu shot 3 weeks ago." *Id.* at 21. He commented that it was "unclear what the etiology of all that was although it seems to have been some sort of severe adverse reaction involving total body weakness." *Id.* He planned to perform a spinal MRI, additional bloodwork, and an EMG. *Id.* An MRI of the thoracic spine was performed the following day and revealed a small central cord syrinx,[9] mild disc disease, and a cyst in Petitioner's right kidney. *Id.* at 24.

In a follow-up appointment with Dr. Lichtenstein on October 13, 2014, Petitioner reported coldness in her right arm but stated that she "otherwise [felt] well." Ex. 17 at 12. Dr. Lichtenstein determined that the right arm tremor had resolved. *Id*. at 11. That same day, Petitioner underwent an EEG, which was normal both awake and asleep. Ex. 22 at 22.

Petitioner saw Dr. Capozzoli in follow-up on November 11, 2014. Ex. 22 at 13. Dr. Capozzoli noted that Petitioner had "bounced back from that rather abruptly and completely and currently [was] without symptoms." *Id*. He remarked that Petitioner's reaction "simulated an acute fulminant GBS although this [was] by no means clear." *Id*. at 15. Her exam was normal, and with Petitioner's report that she "[felt] like she [was] back to baseline," Dr. Capozzoli did not believe a follow-up visit was necessary. *Id*. at 13, 15.

Petitioner saw Dr. Lichtenstein on February 23, 2015, for radiating pain down her right arm. Ex. 17 at 8. Dr. Lichtenstein assessed carpal tunnel syndrome and recommended an EMG of the right wrist, along with lab tests for arthritis. *Id*. at 10.

Petitioner returned to Dr. Capozzoli on February 27, 2015, for her right arm pain. Ex. 22 at 6. Dr. Capozzoli again noted that Petitioner had "completely recovered" from her earlier "severe reaction to a flu shot." *Id*. at 9. He performed an EMG/NCS of Petitioner's right upper extremity, which was normal. *Id*. at 11. He advised Petitioner to wear a wrist splint for one month. *Id.* at 9.

On March 24, 2015, Petitioner saw Dr. Lichtenstein, complaining of right forearm pain. Ex. 17 at 5. Her ROS was otherwise negative. *Id.* at 6. Following an ultrasound of the right shoulder and right elbow, Dr. Lichtenstein diagnosed lateral epicondylitis of the elbow, advised Petitioner to wear a tennis elbow splint, and prescribed Voltaren gel. *Id*. at 7.

[9] A syrinx is an abnormal cavity in the spinal cord in syringomyelia. DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=48643&searchterm=syrinx (last visited October 16, 2024).

On June 30, 2015, about nine months after the subject vaccinations, Petitioner had an initial consultation with Walter E. Kozachuk, M.D.,[10] of The Neuroscience Team, upon referral by her then-counsel. Ex. 25 at 8, 43. She reported that three hours after her flu and pneumococcal vaccinations, she "developed progressive severe swelling and pain of the left deltoid muscle," progressive fatigue, and loss of consciousness. *Id.* at 8. She was hospitalized and intubated. *Id.* Her left arm pain persisted for several weeks and had since "crossed over to the right arm." *Id.* at 9. An exam revealed "mild bilateral VI nerve palsy" and weakness of the right arm. *Id.* at 10. Dr. Kozachuk's clinical impressions included post-vaccination encephalopathy, post-vaccination increased intracranial pressure, cognitive dysfunction with severe decreased recent memory, dysphasia, and "[a]bnormal neurological examination."[11] *Id.* at 10-11. He wrote that "[t]he patient's symptoms show[ed] direct causation to the vaccination[.]" *Id*. at 11.

On July 6, 2015, Petitioner presented to the AAMC ER for a ruptured ovarian cyst, fatigue, and lethargy. Ex. 29 at 306-07. She stated that the cyst had ruptured the previous day. *Id.* at 307. She reported having trouble walking due to leg weakness, and she said that her brain felt "foggy." *Id.* She had undergone an EEG conducted by The Neuroscience Team earlier that day, but she did not know the results. *Id.* On a triage exam, she was noted to have "[s]low responses with fatigued appearance." *Id.* However, a later exam in the ER found that she was alert and oriented, with no cranial nerve deficits. *Id.* at 308-09. She reported that her symptoms

[10] Dr. Kozachuk was discredited in the Vaccine Program after he was reprimanded and placed on probation by the Maryland Medical Board for selling controlled substances. His behavior was described by the Board as "a flagrant abandonment of professionalism." *See Dixon-Jones v. Sec'y of Health & Hum. Servs.*, No. 14-934V, 2019 WL 7556374, *41 (Fed. Cl. Spec. Mstr. Sept. 4, 2019). The disciplinary action against Dr. Kozachuk was upheld by the Court of Appeals of Maryland. *Kozachuk v. Maryland State Board of Physicians* (Dec. 13, 2017) https://www.mbp.state.md.us/bpqapp/Orders/D3727904.256.PDF (last visited October 16, 2024).

[11] In their entirety, Dr. Kozachuk's impressions were: (1) post-vaccination encephalopathy with fever, cognitive dysfunction, distal weakness, and respiratory distress; (2) post-vaccination left shoulder pain and swelling; (3) post-vaccination bilateral distal extremity numbness and paresthesias; (4) right upper extremity radiculitis from the right deltoid to the elbow; (5) bilateral arm dysesthesias (R>L); rule out post-vaccination polyradiculopathy; (6) distal right upper extremity pain; (7) right upper extremity tremor: resolved for two weeks; (8) numbness and paresthesias of the hands; (9) post-vaccination increased intracranial pressure with opening pressure of 33 cm H_20 consistent with the clinical symptoms of cognitive dysfunction; (10) cognitive dysfunction with severe decreased recent memory: consistent with PRES (posterior brain dysfunction) due to vaccination or residual increased intracranial pressure (prior to closing pressure was 19 cm H_20); (11) dysphasia with occasional word finding difficulty: consistent with left hemisphere dysfunction; (12) episodes of severe coldness of the right distal arm; (13) dysgraphia secondary to right hand weakness; (14) abnormal lab results of increased WBC with shift to the left; increased CRP and ESR and increased total complement: consistent with peripheral inflammatory reaction; (15) abnormal neurological examination with bilateral VI nerve palsy, abnormal Weber and Rinne's tests to the right: disequilibrium with abnormal Romberg sign and single leg standing, atrophy of the right hand with weakness of the right distal upper extremity and abnormal reflexes which are increased in the lower extremities (left greater than right): the VI nerve palsy and abnormal reflexes are consistent with increased intracranial pressure; and (16) that the patient's symptoms show direct causation to the vaccination of September 22, 2014. Ex. 25 at 10-11.

had resolved since she presented to the ER, and she was discharged home. *Id.* at 311. She had a brain MRI without contrast on July 8, 2015, which was normal. *Id.* at 341-42.

The July 6, 2015 EEG performed by The Neuroscience Team was interpreted by neuropsychologist Gabriel Newman, Ph.D., to indicate "dysregulation," along with a "possible hydrocephalic condition." Ex. 1 at 326-27.

On July 10, 2015, Petitioner underwent an LP at AAMC performed by Kerry Thompson, M.D., on referral from Dr. Kozachuk. Ex. 29 at 356. The indication for the procedure was an "overall concern for symptomatic intracranial hypertension." *Id.* At the time of the LP, Petitioner denied dizziness, headache, nausea, or blurred vision. *Id.* at 353. The opening pressure of the CSF during the test was elevated. *Id.* at 357.

On July 17, 2015, Petitioner underwent another EMG/NCS, which showed a median neuropathy of both wrists but was otherwise normal. Ex. 25 at 12-13.

On July 27 and 30, 2015, Dr. Newman performed a neuropsychological evaluation of Petitioner. Ex. 25 at 14. Dr. Newman claimed that Petitioner suffered from a host of problems, and he concluded "with reasonable neuropsychological probability that the cause was the simultaneous administration of the flu and pneumonia vaccine generating brain inflammation." *Id*. at 28.

On August 6, 2015, Petitioner had another "quantitative" EEG, which was administered by Dr. Newman. Ex. 25 at 36. Dr. Newman stated that Petitioner's results were "deviant from normal," and he advised her to consult a specialist in CSF abnormalities. *Id*. at 37.

On August 10, 2015, Petitioner had another LP performed due to headache and "encephalitis." Ex. 11 at 6. The opening and closing pressures of the CSF were within normal limits. *Id.*

Petitioner saw ENT Matthew Hilburn, M.D., on August 25, 2015, complaining of ear pain. Ex. 6 at 9. An exam, which included assessment of the cranial nerves, was normal. *Id.* Dr. Hilburn could not determine the cause of Petitioner's ear pain. *Id.* He surmised that the pain could be referred "from chronic headaches stemming from her vaccine reaction or even from temporomandibular joint disease." *Id.* at 9-10.

On September 21, 2015, Petitioner saw Dr. Hilburn for a follow-up visit. Ex. 6 at 11. Again, her physical exam was "fairly benign," and tympanometry showed "no evidence of Eustachian tube dysfunction." *Id.* at 12. An audiogram, however, showed mild-to-moderate sensorineural hearing loss. *Id.* Dr. Hilburn "assume[d] that her hearing loss [was] somewhat tied up with the neurologic sequelae that she had after her flu vaccine reaction," and he also suspected that she had "some degree of temporomandibular joint disease." *Id.*

On October 28, 2015, Petitioner had an annual eye exam. Ex. 9 at 2. She complained of blurry vision and feeling "foggy." *Id.* The exam showed normal results for the fundus, visual field testing, and optical coherence tomography. *Id.* at 3-4. The impression was suspected

glaucoma and vitreous floaters. *Id.* at 4.

Petitioner became pregnant in late 2015, and she delivered a healthy baby girl without complications on July 21, 2016. Ex. 29 at 448-632. On January 4, 2017, Petitioner presented to Nurse Sonya Williams at Maryland Primary Care Physicians, with chief complaints of "adverse reaction to flu vaccine" and sinus pressure. Ex. 20 at 8. Petitioner reported that she was pregnant again, and she was worried that her encephalopathy symptoms were returning. *Id.* at 10. She said she was scheduled to be seen by her "neuropsychiatrist and neurosurgeon." *Id.*

On March 8, 2017, Petitioner saw orthopedist and hand surgeon Alexander Shushan, M.D., at Anne Arundel Medical Group, complaining of "sudden onset of numbness, tingling, weakness in the right hand." Ex. 10 at 8. An exam revealed a positive Phalen's test at the wrist level and a positive carpal compression test. *Id.* Petitioner asked Dr. Shushan whether her carpal tunnel syndrome could have been caused by the flu vaccine, and Dr. Shushan explained that "no specific correlation could be made," but "if she had underlying post viral/vaccine encephalopathy and developed on top of that a carpal tunnel syndrome, [] treatment of the carpal tunnel in the face of an underlying encephalopathy can oftentimes improve overall function of the hand and condition of the hand." *Id.* at 9.

On April 26, 2017, Petitioner saw neurologist Paul Dash, M.D., at a Johns Hopkins Medical Center clinic. Ex. 18 at 5-8. After reviewing Petitioner's medical history and upon physical examination, Dr. Dash could find "no evident cognitive defects" and determined that Petitioner likely had a functional neurological disorder, noting that her "story [was] bizarre." *Id.* at 7. He observed that there were functional sensory findings on exam, including over the face and right hand. *Id.* Dr. Dash also suspected that Petitioner might have a component of fibromyalgia, which would account for her fatigue and diffuse aches. *Id.*

Petitioner became pregnant again in 2018 and attended regular prenatal visits. *See generally* Ex. 3. She underwent right carpal tunnel release surgery on October 25, 2019. Ex. 37 at 10. On February 5, 2020, she presented to the University of Maryland Shore Emergency Center with complaints of a ten-day, left-sided headache, new slight facial droop on the right side, and right-sided facial pain. Ex. 40 at 2, 31, 35. She reported being prescribed Augmentin and prednisone the previous week for a sinus infection. *Id.* at 35. She was diagnosed with a non-intractable headache, facial droop, and sinusitis. *Id.* at 2, 31. Her facial droop resolved that evening. *Id.* at 39. The next day, an MRI of the brain, with and without contrast, was normal except for signs of acute sinusitis. Ex. 42 at 56.

On February 7, 2020, Petitioner saw the expert she retained in this case, Carlo Tornatore, M.D., at Georgetown University Hospital. Ex. 42 at 52. She was seen on a "semi-emergent" basis, complaining of a two-week history of right temporal pain, along with right-sided facial weakness and numbness over the prior three days.[12] *Id.* Dr. Tornatore commented that Petitioner's "past medical history [was] notable for an adverse reaction to an influenza vaccination [in] 2014 with subsequent development of a cervical syrinx." *Id.* at 53. On exam,

[12] This visit was recorded as a "follow-up," but Petitioner did not produce any record of an earlier visit with Dr. Tornatore. Ex. 42 at 52.

Dr. Tornatore observed no cranial nerve abnormalities or papilledema. *Id.* He assessed chronic paroxysmal hemicrania and Chiari malformation, type I.[13] *Id.* at 54. He suspected that her cranial pain was "secondary to the sinus infection which [had] been only partially if at all treated with subsequent quite severe cephalgia." *Id.* He did not diagnose intracranial hypertension. He prescribed a course of antibiotics, along with Oxycodone and Clonazepam to use as needed. *Id.* He also planned a cervical spine MRI to assess whether there had been any progression or regression of the cervical syrinx. *Id.*

Four days later, on February 11, 2020, Petitioner presented to the ER at Georgetown University Hospital. Ex. 42 at 17. She complained of a two-week history of ongoing headache, and she reported developing a fever of 101 degrees that day. *Id.* She believed the headache started with a sinus infection, but she was now concerned she might have developed meningitis. *Id.* On exam, Petitioner was afebrile and had no signs of meningitis. *Id.* at 19. At her request, she was referred for a neurology consult. *Id.*

Later that day, Petitioner was seen by neurologists Bilaal Sirdar, M.D., and Nathan Lightfoot, D.O. Ex. 42 at 3. Petitioner reported "worsening headache" and "reported fever at home." *Id.* She stated that the headaches began about two weeks prior, and she was diagnosed with sinusitis. *Id.* She had seen Dr. Tornatore for the sinusitis and was prescribed antibiotics. *Id.* She had been taking NSAIDs and Tylenol in large doses for her headaches, but it was "without great effect." *Id.* She was told that if she developed a fever or worsening headache to go to the ER because "she may have meningitis." *Id.* at 18. A neurological exam was normal. *Id.* at 5-6, 18. Drs. Sirdar and Lightfoot suspected that Petitioner started with a sinus headache but then developed an analgesic headache secondary to medication overuse. *Id.* at 6, *see id* at 3. They advised her to take Naproxen twice daily for one week, along with Reglan and Benadryl. *Id.* at 3.

No other medical records were filed that pertain to Petitioner's alleged injury.

III. Expert Opinions

A. Dr. Tornatore's First Expert Report

Dr. Tornatore authored four reports in this case. *See* Ex. 30 ("First Tornatore Rep."); Ex. 34 ("Second Tornatore Rep."); Ex. 38 ("Third Tornatore Rep."); Ex. 46 ("Fourth Tornatore Rep.").

Dr. Tornatore earned an M.S. in physiology from Georgetown University in 1982. Ex. 43 ("Tornatore CV") at 2. He earned his M.D. from Georgetown in 1986. *Id.* He completed his residency in neurology at Georgetown University Hospital and a fellowship in molecular virology at the National Institutes of Health. *Id.* He is board certified in neurology and licensed to practice medicine in Washington, D.C. *Id.* at 1. He is a Professor and Chairman of the Department of

[13] Chiari I malformation is defined as a prolapse of the cerebellar tonsils into the spinal canal without elongation of the brainstem. It is often asymptomatic. DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=119469&searchterm=Chiari+I+malformation (last visited October 16, 2024).

Neurology at Georgetown University Medical Center, and Chairman and Neurologist-In-Chief of the Department of Neurology at Georgetown University Hospital. *Id.* He is also the Director of the Georgetown University Hospital Neurology residency program, clerkship program, multiple sclerosis clinic, and spasticity clinic. *Id.* at 3-4. He oversees the research endeavors of fifteen laboratories, employing nineteen principal investigators and more than ninety post-doctoral fellows, doctoral candidates, graduate students, and lab technicians. First Tornatore Rep. at 1. He is also an ad hoc reviewer for numerous journals, including *Annals of Neurology, Neurology, Medical Virology, Journal of Neurovirology,* and *Gene.* Tornatore CV at 7.

Dr. Tornatore opined that Petitioner suffered two "related events that can explain all of [her] acute and chronic symptoms: 1) Vaccine induced Type III hypersensitivity reaction with systemic inflammation [and] 2) Secondary intracranial hypertension induced by Type III hypersensitivity [with] systemic inflammation[.]" First Tornatore Rep. at 15.

Dr. Tornatore maintained that shortly after Petitioner was vaccinated, she "had the onset of symptoms consistent with a Type III hypersensitivity reaction, or what her treating physicians called serum sickness." First Tornatore Rep. at 15. A Type III hypersensitivity reaction is "mediated by antigen-antibody-complement (immune) complexes that are formed when the antigen is found in tissues or blood in moderate antigen excess." *Id.* at 16 (quoting BELLANTI ET. AL. IMMUNOLOGY IV: CLINICAL APPLICATIONS IN HEALTH AND DISEASE (2012) (filed as Ex. 45) ("Bellanti"). This mechanism of immunologic injury "has great clinical significance and forms the basis for a wide variety of disorders," ranging from localized to systemic disease. *Id.* Immune complexes are formed in response to an antigen. *Id*. These complexes are vital to regulating the immune response. *Id.* They also, however, can "participate in the pathologic expression of immune complex disease." *Id.* When antibody production surpasses antigen concentration later in the immune response, the immune complexes can become capable of suppressing antibody production, through their capacity to avidly bind to immunoglobulin Fc receptors, complement receptors, and mononuclear phagocytic cells. *Id.* When an antigen remains and is present in high quantities, pathologic sequelae can result. *Id.*

Immune complex pathology can cause two types of tissue injuries. First Tornatore Rep. at 16 (citing Bellanti). A Type IIIA, or an "Arthus," reaction is localized, while a Type IIIB reaction is systemic and may manifest as "serum sickness." *Id.* Such reactions usually follow the repeated injections of an antigenic substance, like a vaccine, into the skin or tissues of a previously immunized individual. *Id.* The resulting immune complexes deposit in and around the vascular endothelium of the small blood vessels of the skin, initiating a sequence of destructive inflammatory reactions "within 4 to 10 hours," characterized by localized vasculitis with neutrophil infiltration and extravasation of fluid and blood cells into the tissues. *Id.*

According to Dr. Tornatore, Petitioner's medical course indicated a vaccine-induced hypersensitivity reaction "with systemic inflammation." First Tornatore Rep. at 15. Most notably, she had a fever for several days, pain and erythema at the vaccination site, and multiple lab values consistent with such a reaction, including elevated WBC, CRP, and ESR. *Id.*

Dr. Tornatore opined that this reaction, in turn, caused her to develop intracranial hypertension ("IH"). First Tornatore Rep. at 17. IH is caused by obstruction of the flow of CSF.

Id. CSF is produced by the choroid plexus in the ventricles of the brain. *Id.* It moves through a path in the brain and is absorbed by small vessels in the arachnoid tissue called arachnoid granulations. *Id.* After passing through the arachnoid granulations, the CSF enters the venous drainage of the brain, which in turn drains into the right side of the heart. *Id.* Anything that blocks the arachnoid granulations will cause the CSF to back up, leading to increased intracranial pressure. *Id.* The diagnosis of idiopathic IH is assigned where there is no determined cause for the CSF blockage, while secondary IH is assigned where there is an identifiable cause. *Id*.

Symptoms of increased intracranial pressure include headache, visual changes, abducens (VI) nerve palsy,[14] tinnitus, hearing changes, vertigo, and cognitive changes. First Tornatore Rep. at 16-17 (citing Julayanont et al., *Idiopathic Intracranial Hypertension: Ongoing Clinical Challenges and Future Prospects*, J. PAIN RES. 87, 88 (2016) (filed as Ex. 32) ("Julayanont")). Cognitive symptoms can include impaired "memory, executive function, visuospatial processing, attention, motor skills, working memory, and processing speed." *Id.* at 17. According to Dr. Tornatore, Petitioner "had many of these signs and symptoms and had elevated CSF pressure on 2 separate occasions almost 10 months apart. Most notably, she had transient improvement in the symptoms after lumbar puncture with drainage of the CSF." *Id.* One of her treating physicians, Dr. Kozachuk, also found that Petitioner had features of increased intracranial pressure. *Id*. Petitioner might have been predisposed to IH because her BMI was in the obese range. *Id.* at 18.

Dr. Tornatore opined that "it is biologically plausible" that the circulating antigen-antibody complexes produced during a Type III hypersensitivity reaction could cause IH by depositing in the arachnoid granulation vessels, leading to diminished CSF absorption and increased intracranial pressure. First Tornatore Rep. at 18. He pointed to a case report discussing a patient with systemic lupus erythematosus ("SLE") who presented with IH. *Id.*; Yadav et al., *Intracranial Hypertension: A Rare Presentation of Lupus Nephritis*, 5 J. PEDIATRIC NEUROSCIENCE 1, 3 (2010) (filed as Ex. 31) ("Yadav").

Dr. Tornatore concluded that Petitioner had an acute reaction to the flu and Pneumovax vaccinations she received on September 22, 2014, characterized by a marked systemic inflammatory response and the onset and persistence of increased intracranial pressure. First Tornatore Rep. at 15. Petitioner's symptoms developed within the timeframe associated with a Type III hypersensitivity reaction. *Id.* at 18. Dr. Tornatore opined that Petitioner's symptoms were more likely caused by the flu vaccine, because (according to a report made by Petitioner to a medical provider) she previously received that vaccination, predisposing her to a subsequent Type III hypersensitivity reaction. *Id.*

B. Dr. Callaghan's First Expert Report

Dr. Callaghan authored three expert reports. *See* Ex. A ("First Callaghan Rep."); Ex. B ("Second Callaghan Rep."); Ex. C ("Third Callaghan Rep.").

[14] Abducens nerve palsy is a paralysis of the lateral rectus muscle of the eye due to a lesion of the abducens nerve, with internal strabismus and diplopia. DORLAND'S, https://www.dorlandsonline.com/dorland/definition ?id=95777 (last visited October 16, 2024).

Dr. Callaghan earned his M.D. from the University of Pennsylvania in 2004. Ex. D ("Callaghan CV") at 1. In 2011, he earned an M.S. in clinical research design and statistical analysis from the University of Michigan. *Id.* He completed his residency in neurology at the University of Pennsylvania and two fellowships at the University of Michigan. *Id*. He is board certified in neurology and electrodiagnostic medicine. *Id.* He is a Professor at the University of Michigan and serves as a staff physician in the Neurology Department of the VA Ann Arbor Healthcare system. *Id.* He is also the Director of the VA Ann Arbor Healthcare system's ALS Clinic. *Id.* at 1-2. He is actively involved in research and is a journal reviewer for multiple publications, including *Annals of Neurology, Brain, Brain and Behavior, Diabetes, Lancet,* and *Neurology*. *Id.* at 2-6. He has published more than 120 peer-reviewed papers and three book chapters. *Id.* at 14-20.

Dr. Callaghan concluded that Petitioner's course was explained by a functional neurologic disorder. First Callaghan Rep. at 6. She had a pre-vaccination neurological history significant for paradoxical vocal cord mobility and intermittent dyspnea, as well as chest tightness, globus sensation, trouble swallowing, and labial pain, all of unknown cause. *Id.* at 5. During her hospitalization the day after vaccination, several of her treating physicians suspected a psychogenic component of her symptoms, given her inability to move anything but her eyes, but intact awareness, as well as the fact that she was intubated, then promptly extubated after showing sudden improvement. *Id.* Following this incident, Petitioner seemingly had a full recovery, with resolution of all her symptoms. *Id.* Her MRI and LP were normal. *Id.* She had no additional complaints, except for a small syrinx, until she presented to Dr. Kozachuk at the Neuroscience Team nine months after vaccination. *Id.* Also, Petitioner had a very similar presentation in July 2015, when she suffered a ruptured ovarian cyst. *Id.* She reportedly was unable to move or speak and seemed to lose consciousness. *Id.* And Johns Hopkins neurologist Dr. Dash characterized her story as "bizarre" and diagnosed a functional disorder, perhaps overlaid with fibromyalgia. *Id.*

Dr. Callaghan disagreed with the findings made by the Neuroscience Team practitioners, stating that their practice was "very different than the care I provide to my patients and very different than the care that would be provided at most reputable medical institutions." First Callaghan Rep. at 6. He commented that Dr. Kozachuk's credibility was "called into question by his report of 30 diagnoses [assigned to Petitioner] that do not make sense." *Id.* For example, Dr. Kozachuk's reading of Petitioner's EEG was inappropriate, as was the fact that absence seizures were purportedly observed but not treated with antiepileptic medications.[15] *Id.* His conclusion that Petitioner had an "autoimmune neuropathy" in the right hand only was also erroneous, because "[a]utoimmune neuropathies, such as GBS, present with symptoms in 4 limbs rather than confined to the right arm." *Id.*

[15] Dr. Callaghan also criticized Dr. Newman's evaluations of Petitioner, noting that he performed an unvalidated "quantitative EEG" test, which provided results inconsistent with Petitioner's presentation. First Callaghan Rep. at 7. An EEG done by a qualified neurologist was normal. *Id.* "Furthermore, quantitative EEG cannot be used to diagnose a hydrocephalic condition," and Petitioner "did not have hydrocephalus on MRI." *Id.*

Dr. Callaghan opined that the diagnosis of IH in Petitioner was incorrect. First Callaghan Rep. at 6. The diagnostic criteria for IH are papilledema,[16] normal neurologic examination (excluding VI nerve palsy), normal neuroimaging, normal CSF, and a CSF pressure over 25. *Id.* at 5-6; Mollan et al., *Idiopathic Intracranial Hypertension: Consensus Guidelines on Management*, 89 J. NEUROLOGY, NEUROSURGERY & PSYCHIATRY 1088, 1091 (2018) (filed as Ex. A, Tab 1) ("Mollan"). Petitioner did not exhibit papilledema at any time. Callaghan Rep. at 6. Petitioner also had no signs of IH on MRI. *Id.* Furthermore, although there are literature reports of a subset of idiopathic IH cases without papilledema ("IIHWOP"), Dr. Callaghan characterized this diagnosis as "controversial" and not yet accepted by the medical community. *Id.* And even if this were a valid diagnosis, it requires a finding of VI nerve palsy, which was not observed by any of Petitioner's physicians, except Drs. Kozachuk and Newman. *Id.*; *see also* Second Callaghan Rep. at 1.

According to Dr. Callaghan, "[n]o data exist[] to demonstrate a causal association between [IH] and vaccination." First Callaghan Rep. at 7. There are no epidemiologic studies or case reports documenting such an association. *Id.* "Furthermore, no biologic mechanisms have been proposed to link [IH] and vaccination." *Id.*

C. Dr. Tornatore's Second Expert Report

In response to Dr. Callaghan's opinion that Petitioner did not meet the criteria for IH, Dr. Tornatore stated that (1) Petitioner had markedly elevated CSF pressure on two occasions; (2) one of her physicians (Dr. Kozachuk) found bilateral VI nerve palsies; (3) several physicians diagnosed IH; and (4) papilledema is not a requirement for IH, given the recognition of IIHWOP. Second Tornatore Rep. at 2 (citing Digre et al., *A Comparison of Idiopathic Intracranial Hypertension With and Without Papilledema*, 49 HEADACHE 185, 186 (2009) (filed as Ex. 35) ("Digre")).

Dr. Tornatore also disputed Dr. Callaghan's conclusion that Petitioner suffered from a functional neurological disorder. Second Tornatore Rep. at 3. He noted that she had objective symptoms indicating an organic illness. *Id.* She also had a negative psychiatric evaluation in the hospital. *Id.*

Dr. Tornatore opined that there is a biological mechanism by which vaccine-caused serum sickness could induce IH. Second Tornatore Rep. at 3. He cited a 1981 paper by Dr. James Donaldson discussing the association of "serum sickness" with IH. *Id.*; Donaldson, *Pathogenesis of Pseudotumor Cerebri Syndromes*, 31 NEUROLOGY 877, 879 (1981) (filed as Ex. 36) ("Donaldson"). He concluded that "[i]n aggregate, there is a scientifically recognized mechanism that can account for the development of intracranial hypertension in this case." *Id.*

[16] Defined as edema of the optic disk (papilla), most commonly due to increased intracranial pressure, malignant hypertension, or thrombosis of the central retinal vein. DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=36673&searchterm=papilledema (last visited October 16, 2024).

D. Dr. Callaghan's Second Expert Report

Dr. Callaghan maintained that the criteria for IH were not satisfied because no credible physician ever observed a VI nerve palsy. Second Callaghan Rep. at 1. With respect to Petitioner's initial post-vaccination presentation, he agreed that she had symptoms indicative of a "transient infection or inflammatory process," but the cause of those symptoms was unclear. *Id.* The symptoms could have been "related to her recent upper respiratory infection as documented in her visit to her primary care physician on 9/9/14[.]" *Id.* No medical record supported vaccination as the cause of this transient process. *Id.* And even if the vaccination were involved, "there is no evidence that a transient infectious or inflammatory process would lead to [Petitioner's] subsequent symptoms." *Id.* at 1-2. Also, the existence of a transient infectious or inflammatory process would not preclude a concurrent functional neurologic condition. *Id*. at 2.

Dr. Callaghan asserted that the Donaldson paper discusses a potential association between serum sickness and IH, but Petitioner "did not have serum sickness" or IH. Second Callaghan Rep. at 2. Moreover, "the mechanism of [IH] is still unknown today with many potential mechanisms, but not any that are definitive," and pathogenic immune complexes are not one of the proposed mechanisms. *Id.*

E. Dr. Tornatore's Third Expert Report

Dr. Tornatore reiterated his opinion that Petitioner had the symptoms of IH, including VI nerve palsy diagnosed by her treating physicians (Drs. Kozachuk and Newman). Third Tornatore Rep. at 1. Furthermore, "[e]ven if we exclude Dr. Kowachuk's [sic] examination, one cannot deny that she had objective evidence of increased [CSF] pressures on two separate occasions when [LP] was performed, including during her initial hospitalization." *Id.* at 2.

Dr. Tornatore also pointed out that Petitioner's treating infectious disease physician believed her initial presentation was vaccine-caused. Third Tornatore Rep. at 2. He disputed Dr. Callaghan's characterization of Petitioner's illness as "transient," citing the fact that she had two elevated CSF pressure measurements ten months apart, neither of which were recorded by Neuroscience Team doctors. *Id.* He noted that persistent increases in CSF pressures can "result in cognitive dysfunction," which Petitioner exhibited during neurocognitive testing in July 2015. *Id.* (citing Julayanont).

Dr. Tornatore disagreed with Dr. Callaghan's contention that Petitioner had a functional neurologic disorder. Third Tornatore Rep. at 3. Petitioner initially presented with fever, elevated WBC count with neutrophilia, and elevated CRP and ESR, all of which show an organic basis for her neurologic symptoms. *Id*. He reasserted that a psychiatric consult did not identify a functional neurologic cause. *Id.* Petitioner's two spinal taps also showed elevated CSF pressures. *Id*. In the aggregate, the medical record was "replete with evidence that Petitioner had organic causes for her symptomatology." *Id.*

Although Dr. Callaghan did not believe that Petitioner had serum sickness, Dr. Tornatore pointed out that her treating infectious disease specialist did suspect this. *Id*. Serum sickness-like reactions have previously been reported following flu vaccination. Apisarnthanarak et al., *Serum*

Sickness–Like Reaction Associated with Inactivated Influenza Vaccination among Thai Health Care Personnel: Risk Factors and Outcomes, Clinical Infectious Diseases e18, e21 (2009) (filed as Ex. 39) ("Apisarnthanarak").

Finally, Dr. Tornatore did not find it surprising that no epidemiologic study reported a causal association between vaccination and IH. Third Tornatore Rep. at 4. He stated that epidemiology cannot rule out a rare event such as a vaccine-related injury. *Id.*

F. Dr. Callaghan's Third Expert Report

In his third expert report, Dr. Callaghan addressed questions from the former special master. Third Callaghan Rep. at 1. He first explained that a VI nerve palsy is "an injury to the sixth cranial nerve that controls abduction of the eye." *Id*. This would present as the inability to look to the right with the right eye only, as well as horizontal double vision. *Id.* Dr. Callaghan doubted the finding of VI nerve palsy by the Neuroscience Team doctors, in part because Petitioner had normal neurological and ophthalmological exams on numerous occasions.[17] *Id.* at 1-2. He also felt that such a finding would not likely be related to the vaccinations Petitioner received nine months before that observation was made. *Id.* at 1-2.

More generally, Petitioner did not have "the typical symptoms" of IH and had a variety of other, unexplained symptoms, including functional findings, and she had symptoms similar to her post-vaccination complaints after her ruptured ovarian cyst in July 2015. Third Callaghan Rep. at 2.

Finally, Dr. Callaghan opined that Petitioner "never had markedly elevated [CSF] pressure." Third Callaghan Rep. at 3. He stated that she had one mildly elevated pressure reading, with unknown cause, and one normal reading. *Id.*

G. Dr. Tornatore's Fourth Expert Report

In Dr. Tornatore's last report, he too addressed questions from the former special master. Fourth Tornatore Rep. at 2-4. Asked whether he agreed that a VI nerve palsy is a required finding in a diagnosis of IIHWOP, he clarified that he believed Petitioner had secondary IH, not idiopathic IH. *Id.* Nonetheless, he found the IIHWOP criteria provided a "useful framework" for the diagnostic analysis. *Id.* He disagreed that VI nerve palsy is a requirement for the IIHWOP diagnosis. *See* Digre at 186; *see also* Wall, *Idiopathic Intracranial Hypertension*, 28 NEUROLOGIC CLINICS 1, 4 (2010) (filed as Ex. 47) ("Wall"). Rather, the presence of a VI nerve palsy suggests that the increased intracranial pressure could be due to something other than an idiopathic origin. Fourth Tornatore Rep. at 2.

[17] Specifically, Dr. Callaghan explained that Petitioner had a normal "fundus examination" looking for papilledema. Third Callaghan Rep. at 2. She also had normal optical coherence tomography testing, which looked for abnormalities in the thickness of the retina and optic nerve head. *Id.*

Dr. Tornatore did not believe that Petitioner's negative MRI findings would rule out IIHWOP. Fourth Tornatore Rep. at 2-3; Digre at 186. The majority of his own patients with idiopathic IH had normal neuroimaging. Fourth Tornatore Rep. at 3.

Dr. Tornatore was asked about the findings of Petitioner's treating physicians and how they fit with the theory of his case. Fourth Tornatore Rep. at 3. Specifically, on November 4, 2014, and February 27, 2015, Dr. Capozzoli documented that Petitioner "had bounced back … rather abruptly and completely and currently [was] without symptoms." Ex. 22 at 13. Dr. Tornatore opined that Petitioner's medical records speak to an acute post-vaccinal inflammatory process, which led to secondary IH caused by obstruction of CSF circulation by inflammatory products. Fourth Tornatore Rep. at 3; Donaldson at 879. As the inflammatory process abated, the CSF dynamics improved due to better drainage through the arachnoid granulations, which alleviated Petitioner's symptoms. Fourth Tornatore Rep. at 3. However, the CSF dynamics never completely normalized, as evidenced by two separate CSF pressure readings in the elevated range on September 24, 2014, and July 10, 2015. Ex. 29 at 153, 357. Dr. Tornatore concluded that a patient can have symptom resolution despite the persistence of elevated CSF, as was the case for Petitioner. Fourth Tornatore Rep. at 4.

H. Dr. MacGinnitie's Expert Report

Dr. MacGinnitie authored one expert report in this case. *See* Ex. E ("MacGinnitie Rep.").

Dr. MacGinnitie received a Ph.D. in pathology in 1996, and an M.D. in 1998, from the University of Chicago Pritzker School of Medicine. Ex. F ("MacGinnitie CV") at 1. He completed a residency in Pediatrics, a fellowship in Allergy and Immunology, and a clinical fellowship in Pediatrics, all at Harvard Medical School. *Id*. Until recently, he taught at Harvard Medical School as an Associate Professor of Pediatrics and was an Attending Physician and Clinical Chief of the Division of Immunology at Children's Hospital Boston.[18] *Id.* at 1-2. Dr. MacGinnitie is actively involved in research. *Id.* at 4-5. He has written approximately fifty peer-reviewed articles. *Id.* at 12-17.

Dr. MacGinnitie focused his report on whether Petitioner had "serum sickness," deferring to Dr. Callaghan regarding Petitioner's purported neurologic illnesses. MacGinnitie Rep. at 9. He disagreed with the diagnosis of serum sickness/Type IIIB systemic reaction. *Id.* First, a Type IIIB reaction typically occurs four to ten days after antigenic exposure. *Id.* at 10 (citing Bellanti). An onset minimum of seven days, with an average of nine days, was reported in the Apisarnthanarak paper. *Id.* The onset of Petitioner's symptoms, by contrast, was within four to ten hours of vaccination. *Id.* This was more consistent with a localized Arthus reaction. *Id.*

Second, Petitioner's lab values were inconsistent with serum sickness. MacGinnitie Rep. at 10. The Apisarnthanarak paper reported that patients with serum sickness had decreased C3

[18] Beginning in January 2024, after the record in this case was completed, Dr. MacGinnitie began a new position as a Pediatric Allergy Immunologist Specialist and Professor of Pediatrics at the Medical College of Wisconsin. *See* CHILDREN'S WISCONSIN, https://childrenswi.org/medical-professionals/latest-news/andrew-macginnitie-md (last visited October 16, 2024).

and C4 complement levels. *Id.* The Usman paper similarly noted that such patients have low C3, C4, and CH50 levels. *Id.*; Usman & Annamaraju, *Type III Hypersensitivity Reaction*, StatPearls 1, 5 (2022) (filed as Ex. E, Tab 1) ("Usman"). Petitioner, by contrast, had normal C3 and C4 levels and elevated CH50 levels. MacGinnitie Rep. at 11; *see also* Ex. 29 at 213-15.

Third, serum sickness is a "self-limited process" with symptoms that resolve over days to weeks, not months. MacGinnitie Rep. at 11. Apisarnthanarak and Usman found serum sickness resolved in one to two weeks. *Id.*

Dr. MacGinnitie also disputed Dr. Tornatore's opinion that a Type III reaction could cause IH. MacGinnitie Rep. at 11. He commented that Dr. Tornatore produced only one forty-year-old article discussing an association between serum sickness and IH. *Id*. (citing Donaldson). That paper merely observed that "immune complexes can deposit in the choroid plexus, although how this affects CSF formation is unknown." *Id.*[19] Dr. MacGinnitie found no other literature reporting an association between these conditions. *Id.* The Usman review of Type III hypersensitivity reactions did not report neurologic symptoms caused by such reactions; nor did the Apisarnthanarak paper. *Id.*

IV. Applicable Law

A. Petitioner's Burden in Vaccine Program Cases

Under the Vaccine Act, a petitioner may prevail in one of two ways. First, she may show that she suffered a Table injury within the time provided in the Table. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Second, where the alleged injury is not listed in the Table, she may demonstrate that she suffered an "off-Table" injury that was caused-in-fact by her vaccination. § 11(c)(1)(C)(ii).

For both Table and non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. § 13(a)(1). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010); *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). The petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on her assertions;

[19] Dr. MacGinnitie pointed out that Dr. Tornatore initially argued that serum sickness affects CSF removal through the arachnoid granulations. MacGinnitie Rep. at 11. The Donaldson article, by contrast, contended that serum sickness causes immune complex deposition in the choroid plexus, which is responsible for CSF formation. *Id.*

rather, the petition must be supported by either medical records or the opinion of a competent physician. § 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Secretary of Health and Human Services*. 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires a petitioner to establish by preponderant evidence that the vaccination caused her injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, a petitioner must provide a "reputable medical theory" demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs*., 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549; *Bunting v. Sec'y of Health & Hum. Servs.,* 931 F.2d 867, 873 (Fed. Cir. 1991).

A petitioner may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Despite their expertise, special masters are not empowered by statute to conclusively resolve what are complex scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. However, this does not negate or reduce a petitioner's ultimate burden to establish her entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs*., 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326 (stating that "medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence because they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). However, the existence of medical records and/or statements of treating physician views does not require the special master to adopt their conclusions *per se*. § 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("[T]here is nothing … that mandates that the testimony of a treating physician is sacrosanct–that it must be accepted in its entirety and cannot be rebutted."). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating

physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs*., 100 Fed. Cl. 742, 749 (2011) (it was not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Health & Hum. Servs*., No. 06-522V 2011 WL 1935813, *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically acceptable temporal relationship." *Id.* Thus, a petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs*., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also be consistent with the theory for how the relevant vaccine can cause the alleged injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs*., 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand on other grounds*, 105 Fed. Cl. 353 (2012), *aff'd without op.,* 503 F. App'x 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs*., No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Law Governing Analysis of Fact Evidence

The process for making factual determinations in Vaccine Program cases begins with analyzing the medical records, which are required to be filed with the petition. § 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." § 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 413, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is based on a rational analysis).

Medical records created contemporaneously with the events they describe are generally considered trustworthy, because they "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions," where "accuracy has an extra premium." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1382 (Fed. Cir. 2021) (citing *Cucuras*, 993 F.2d at 1528). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining

their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825, *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) *mot. for rev. denied*, 142 Fed. Cl. 247, 251-52 (2019), *vacated on other grounds and remanded*, 809 Fed. Appx. 843 (Fed. Cir. Apr. 7, 2020).

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony– especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony could be more persuasive than written medical records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); *Lowrie*, 2005 WL 6117475, at *19 ("Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent.") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, the special master should assess each witness's credibility when determining the weight their testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent and compelling." *Sanchez*, 2013 WL 1880825, at *3 (quoting *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808V, 1998 WL 408611, *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *LaLonde v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In deciding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony, a rational analysis must be explicated. *Burns*, 3 F.3d at 417.

C. Analysis of Expert Testimony

Establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of his or her claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony

is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do in other federal judicial proceedings. Those factors are employed by judges to exclude evidence that is unreliable and potentially confusing to a jury. In Vaccine Program cases, these factors are generally used to assess the reliability and weight of scientific evidence. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("[U]niquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted[.]"). The flexible use of the *Daubert* factors to evaluate persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 743.

Respondent frequently offers one or more experts of his own to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). Nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). A "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis special masters must employ in Vaccine Program cases. *Id.* at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("[T]his court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act[.]").

D. Consideration of Medical Literature

Finally, although this decision discusses some but not all the medical literature in detail, I have reviewed and considered all the medical records and literature submitted in this matter. *See Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision."); *Simanski v. Sec'y of Health & Hum. Servs.*, 115 Fed. Cl. 407, 436 (2014) ("[A] Special Master is 'not required to discuss every piece of evidence or testimony in her decision.'") (citation omitted), *aff'd*, 601 F. App'x 982 (Fed. Cir.

2015).

V. The Parties' Arguments

A. Petitioner's Motion

Petitioner argues that her post-vaccination symptoms, as well as the "repeated" suspicion of her treating physicians and the absence of any "functional psychological problems," prove she suffered a "Type III hypersensitivity reaction with systemic inflammation." Motion at 11-12. She notes that Dr. Tornatore diagnosed a Type III hypersensitivity reaction with systemic inflammation based on the facts that she had fever, elevated WBC, CRP, and ESR levels, and pain and redness at the site of vaccination. *Id.* at 13-14. Her infectious disease treating physician, Dr. Yang, "frequently referenced serum sickness as a possible cause for her symptoms," and her discharge diagnosis was "likely serum sickness after receiving vaccinations." *Id.* at 14.

Petitioner further contends that her Type III hypersensitivity reaction caused her to develop secondary IH. Motion at 14. Secondary IH is assessed against criteria applied to the diagnosis of idiopathic IH, which require increased intracranial pressure, headaches, normal CSF results, no focal neurologic deficits, normal neuroimaging, and papilledema. *Id.* Additionally, a form of idiopathic IH without papilledema ("IIHWOP") can occur. *Id.*

More specifically, Petitioner argues that the presence of a VI nerve palsy is not required to diagnose IIHWOP. Motion at 16. She points to the Wall article, which reports that only 10-20% of patients with idiopathic IH exhibited such a palsy. *Id.* (citing Wall at 4). This accords with Dr. Tornatore's clinical experience treating IH patients. *Id.* As such, her diagnosis with secondary IH is "supported even though she did not have a 6th nerve palsy documented by credible treating doctors[.]"[20] *Id.*

Petitioner claims she met "almost all" of the criteria for IH. Motion at 15. She had ongoing headaches, documented increased CSF opening pressures during two LPs done ten months apart, and normal CSF lab testing and neuroimaging. *Id.* She also claims she suffered additional symptoms such as hearing and vision changes, extremity pain and weakness, and cognitive changes. *Id.* She also felt nearly immediate relief when she had LPs releasing CSF pressure. *Id.*

Petitioner argues that Dr. Callaghan's opinion that she suffered from a functional disorder was contrary to the weight of the evidence, as it was based on a "single doctor's report who never actually saw or treated [her]." Motion at 15. She notes that she had objective findings supporting an organic disease and had a negative psychiatric evaluation in the hospital. *Id.* at 15-16.

In addressing causation, Petitioner makes a two-fold argument: (1) that her vaccinations caused-in-fact her initial Type III hypersensitivity reaction; and (2) that this reaction, in turn, caused her to develop secondary IH. Motion at 17-20. On *Althen* prong one, Petitioner first asserts that it is "well-established" that a vaccine can cause either a localized or systemic Type III

[20] In the Motion, Petitioner acknowledges the disciplinary action taken against Dr. Kozachuk and states that she is no longer relying on his records or conclusions in support of her case. Motion at 5.

hypersensitivity reaction characterized by the production of immune complexes. Motion at 17. Such a reaction could range from a localized response to a "more generalized" immune complex disorder like serum sickness. *Id.* Petitioner notes that the Apisarnthanarak paper documented serum sickness-like illnesses in patients who received the inactivated flu vaccine. *Id.* at 18. Additionally, the Bellanti textbook on immunology states that a Type III hypersensitivity reaction can follow the "repeated injections" of an antigenic substance, such as a vaccine, into the skin or tissues of a previously immunized individual. *Id.* at 19.

Second, Petitioner cites Dr. Tornatore's opinion that secondary IH can be caused by a Type III hypersensitivity reaction when circulating immune complexes produced by that reaction block CSF drainage through the arachnoid granulations. Motion at 20. Dr. Tornatore supported this claim with a case report of IH associated with lupus/SLE. *Id.* at 20-21. The authors of that case report posited that the proposed mechanism by which SLE could cause IH included "immune-mediated injury within the arachnoid villi and consequent reduction in CSF absorption or probable hypercoaguable state without overt vascular thrombosis giving rise to micro-obliteration of cerebral arteriolar and venous systems." *Id.* at 21 (citing Yadav at 132-34). Petitioner argues that "[a]though [she] does not have lupus, this article supports Dr. Tornatore's testimony that systemic inflammation from an immune response can lead to intracranial hypertension." *Id.* Dr. Tornatore also cited the Donaldson paper, which hypothesized that serum sickness could lead to immune complex deposition in the choroid plexus responsible for CSF formation and also discussed the "distortion of arachnoid villi in meningitis" as a possible mechanism for IH. *Id.* at 24.

Regarding *Althen* prong two, Petitioner first contends that she developed "flu-like" symptoms within one hour of her vaccinations. Motion at 22. In the hospital, physicians believed she had serum sickness, a form of Type III hypersensitivity reaction. *Id.* Her lab results were consistent with that condition. *Id.* Dr. Tornatore opined that the flu vaccine caused this reaction, because she had previously received flu vaccinations and because the timing of her symptoms fit with such a reaction. *Id.*

Petitioner next argues that there is a logical connection between her vaccinations, her Type III hypersensitivity reaction, and her secondary IH. She notes that she had no prior history of IH before her vaccinations. Motion at 23. She developed increased CSF pressure shortly after the vaccinations. *Id.* Dr. Tornatore explained that this was caused by immune complexes from the Type III reaction leading to decreased CSF absorption. *Id.* at 24. She was also predisposed to IH because of obesity. *Id.* at 26.

Regarding *Althen* prong three, Petitioner argues that the Apisarnthanarak paper reports that, in the VAERS database, the "median duration from vaccination to onset of serum sickness-like reaction was within a 24-hour post-influenza vaccination interval in more than [fifty percent] of US cases." Motion at 27. That paper also reported that the median duration from vaccination to onset of symptoms in patients who had previously received flu vaccinations was one to four days.

Id. Petitioner contends that this timeframe fits with the onset of her pain and flu-like symptoms, which was "within hours after the administration of the vaccines." *Id.* at 27-28.

Petitioner argues that the onset of her IH was, likewise, within hours of vaccination. Motion at 28. She argues that the literature supports this timing in the setting of a Type III hypersensitivity reaction. *Id.* at 28-29.

B. Respondent's Contentions

Respondent first contends that Petitioner has failed to show her symptoms extended for more than six months after vaccination. Response at 25; *see* § 11(c)(1)(D) (requiring a petitioner to prove she suffered the residual effects or complications of her vaccine-caused illness, disability, injury, or condition for more than six months after vaccine administration). Rather, "to the extent [Petitioner] had any adverse effect at all, it appeared to be brief, in the form of a time-limited and localized Arthus reaction." *Id.* Her medical records "repeatedly demonstrate resolution" of her post-vaccination symptoms within a few months. *Id.* Additionally, Dr. MacGinnitie explained that a Type III hypersensitivity reaction would be limited to a period of days and not persist for months. *Id.*

Respondent next argues that Petitioner has failed to prove either of her claimed injuries. Response at 25-26. Instead, "the evidence indicates that [she] experienced a constellation of unrelated symptoms that may be consistent with a functional conversion disorder, which is unrelated to either her flu and/or pneumococcal vaccinations of September 22, 2014." *Id.* at 26. Regarding the claimed "serum sickness"/Type III hypersensitivity reaction, Dr. MacGinnitie explained that "the facts of this case disqualify a serum sickness diagnosis." *Id.* The onset of Petitioner's symptoms was too soon after vaccination to constitute a Type IIIB systemic reaction/serum sickness. *Id.* at 26. Also, her lab values and the duration of her symptoms were inconsistent with this condition. *Id.* Furthermore, the later IH diagnosis was initially made by the Neuroscience Team, whose opinions should be viewed with skepticism. *Id.* According to Dr. Callaghan, Petitioner did not meet the diagnostic criteria for IH, in that she did not exhibit either papilledema or VI nerve palsy, and her CSF pressure readings did not record her physical positioning, casting doubt on their reliability. *Id.* at 26-27.

On *Althen* prong one, Respondent cites Dr. MacGinnitie's opinion that, if Petitioner suffered any Type III hypersensitivity reaction, it would not have been a Type IIIB/serum sickness reaction, based on the timing of onset. Response at 27. Instead, it could only have been a Type IIIA Arthus reaction, "which does not involve systemic availability of immune complex." *Id.* at 27-28. Accordingly, Dr. Tornatore's proposed mechanism for the development of secondary IH caused by a Type IIIB hypersensitivity reaction is inapplicable here. *Id.* at 28. Additionally, the 1981 Donaldson article posited four potential mechanisms for IH, but "Dr. Tornatore's immune complex deposit idea was not even one of those." *Id.* Also, there is no epidemiologic data supporting a causal association between vaccination and IH. *Id.*

Respondent contends that *Althen* prong two is unsatisfied because, as Dr. Callaghan opined, the records demonstrate that Petitioner's initial presentation was "psychogenic in origin," perhaps overlaid with a "transient infection or inflammatory process, which may have been related

to her recent upper respiratory infection." Response at 28. Several treating physicians suspected a psychogenic condition. *Id.* at 28-29. As Dr. MacGinnitie opined, to the extent Petitioner experienced a localized Arthus reaction to her vaccinations, it would not have persisted for many months and could not account for her later symptoms. *Id.* at 29. The records, in fact, demonstrate that Petitioner recovered quickly and completely within a few months. *Id.*

On *Althen* prong three, Respondent cites Dr. MacGinnitie's opinion that a Type IIIB reaction would follow four to ten days after antigenic exposure and be characterized by the systemic circulation of immune complexes. Response at 29. Such a reaction could not take place within mere hours, as occurred here. *Id.* at 29-30. Furthermore, to the extent Petitioner is attempting to claim she had a "Type III" reaction that was somehow distinct from serum sickness, she has failed to submit any evidence of the medically appropriate timeframe for onset of that reaction. *Id.*

C. Petitioner's Reply

Petitioner argues that her case meets the severity requirement because her secondary IH persisted for more than six months. Reply at 1-2. Dr. Tornatore has cited literature supporting the notion that IH can be a chronic condition. *Id.*

Petitioner disputes Dr. MacGinnitie's opinion that the onset of her symptoms was too soon to qualify as a "Type III hypersensitivity reaction with systemic inflammation," because he discusses the appropriate onset of "serum sickness," which she argues is a distinct condition. Reply at 4. She contends that the onset of systemic inflammatory symptoms within twenty-four hours accords with the Apisarnthanarak paper, which reported that the "*median* duration from vaccination to onset of serum sickness-like reaction (which is a type of Type III hypersensitivity reaction) as within a 24-hour post-influenza vaccination interval in more than 50% of US cases." *Id.* (emphasis in original). She also reiterates that the presence of papilledema is no longer required for a diagnosis of IH. *Id.*

Petitioner contends that the lack of epidemiologic data on the causal association between vaccination and Petitioner's diagnoses is "unsurprising" given the rarity of such events. Reply at 5. Finally, Dr. Callaghan's opinion that Petitioner had a functional neurological disorder runs contrary to her in-person psychiatric evaluation in the hospital and Dr. Newman's later assessment. *Id.* at 7.

VI. Analysis

Because Petitioner does not allege an injury listed on the Vaccine Injury Table, her claim is classified as "off-Table." As noted above, to prevail on an "off-Table" claim, Petitioner must prove by preponderant evidence that she suffered an injury that was caused-in-fact by the vaccination at issue. *See Capizzano*, 440 F.3d at 1320.

A. Diagnosis

As a threshold matter, a petitioner must establish she suffered the injury for which she seeks compensation. *Broekelschen*, 618 F.3d at 1346. "The function of a special master is not to 'diagnose' vaccine-related injuries, but instead to determine 'based on the record as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner]'s injury.'" *Andreu*, 569 F.3d at 1382 (quoting *Knudsen*, 35 F.3d at 549). "Although the Vaccine Act does not require absolute precision, it does require the petitioner to establish an injury – the Act specifically creates a claim for compensation for 'vaccine-related injury or death.'" *Stillwell v. Sec'y of Health & Hum. Servs*., 118 Fed. Cl. 47, 56 (2014) (quoting 42.U.S.C. § 300aa-11(c)). Accordingly, the Federal Circuit has concluded that it is "appropriate for the special master to first determine what injury, if any, [is] supported by the evidence presented in the record" before applying a causation analysis pursuant to *Althen*. *Lombardi v. Sec'y of Health & Hum. Servs*., 656 F.3d 1343, 1351-53 (Fed. Cir. 2011).

In this case, Petitioner alleges two interconnected diagnoses. She first argues that, soon after her vaccinations, she suffered a "Type III hypersensitivity reaction with systemic inflammation." This caused her to develop secondary, chronic IH. Based on my review of the record, I find that Petitioner has failed to preponderantly prove she suffered from either of these conditions.

1. Type III Hypersensitivity Reaction/Serum Sickness

The record makes clear that, one day after her September 22, 2014 flu and Pneumovax vaccinations, Petitioner presented to the ER complaining of left arm pain, malaise, fever, and severe headache. Ex. 29 at 131-32. She reported she began feeling bad the previous night. *Id.* at 132. Her affidavit corroborates her contemporaneous reports of when her symptoms started. Ex. 28 at 1. In the hospital, she had objective signs of systemic illness, including fever and elevated WBC, CRP, and ESR levels. Ex. 29 at 133-35. She also exhibited an inability to move and inadequate respiratory effort, prompting the ER physician to intubate her. *Id.* at 131-33, 137, 144. When the sedation from the intubation procedure wore off, however, she immediately began moving her limbs and became agitated, so she was extubated. *Id.* at 137, 144. Her condition was suspected to be psychogenic, but a hospital psychiatrist failed to find a psychiatric explanation. *Id.* at 144, 151-53, 173. Her infectious disease physician in the hospital, Dr. Yang, suspected "serum sickness," and her discharge diagnosis was "likely serum sickness" "after receiving vaccinations." *Id.* at 139, 150, 159, 173.

Dr. Tornatore opined that these facts indicate that Petitioner suffered a "Type III hypersensitivity reaction with systemic inflammation," which was likely caused by her flu vaccination. First Tornatore Rep. at 15. He described such a reaction as the product of antigen-antibody-complement complexes that can develop and circulate following "repeated" immunization with an antigen. *Id.* at 16. But as Respondent's immunology expert,[21] Dr. MacGinnitie, persuasively pointed out, this type of systemic immune complex-mediated reaction would not likely occur within a few hours of vaccination, as happened here. MacGinnitie Rep. at

[21] Dr. Tornatore does not hold himself out as an expert in immunology.

9-10. Rather, even according to the literature produced by Dr. Tornatore, a systemic reaction would have taken at least several days to manifest. *Id.* The Bellanti textbook described a systemic "Type IIIB" reaction as follows:

> [I]njections of large amounts of antigen in unimmunized persons is typically followed four to ten days later by antibody production and formation of soluble immune complexes within the circulation. The circulating immune complexes subsequently deposit in the blood vessels of the skin, joints, kidneys, and/or lungs, fix and activate complement, and lead to symptoms of fever, skin rash, swelling, arthritis, and mild organ damage. . . . This constellation of symptoms [is] termed "serum sickness[.]"

Bellanti at 672-73.

Similarly, in the Apisarnthanarak case series submitted by Dr. Tornatore, which studied "serum sickness-like" reactions in recipients of flu vaccinations, the median onset of systemic symptoms was nine days after vaccination, and the minimum onset was seven days. Apisarnthanarak at e20 (Table 2). Indeed, the authors only classified a post-vaccination reaction as a "serum sickness-like" response if the patient developed symptoms at least three days after vaccination. *Id.* at e18. The Usman paper provided by Dr. MacGinnitie described serum sickness as characterized by rash, arthritis, and fever. Usman at 3. That paper also stated that immune complexes form "after 4-10 days," while symptoms of serum sickness "develop in one to two weeks after exposure to the antigen." *Id*. at 2-3.

Petitioner argues that the Apisarnthanarak authors reported that in the VAERS database, the median onset of "possible" serum sickness following flu vaccination was twenty-four hours. Reply at 4; Apisarnthanarak at e21. But Petitioner did not produce the VAERS data; the comment in Apisarnthanarak does not provide a sound basis to estimate onset. Overall, I find more persuasive Dr. MacGinnitie's opinion that the timing of Petitioner's symptoms was inconsistent with her claimed injury.[22]

[22] The Bellanti textbook explained that a Type IIIA reaction will occur within four to ten hours of exposure in a previously immunized person, while a systemic Type IIIB reaction/serum sickness will occur within four to ten days of exposure to "large amounts of antigen" in a previously unimmunized person. Bellanti at 670-73. Dr. Tornatore presumed that Petitioner had previously been immunized with the flu vaccine, as she reported to Dr. Yang during her initial hospitalization. First Tornatore Rep. at 18; Ex. 29 at 149. However, that single report cannot support a determination that Petitioner had a previous flu vaccination or when it might have been given. Petitioner did not file any vaccination record documenting previous receipt of any type of flu vaccination. Moreover, regardless of Petitioner's vaccination history, the literature filed into the record does not demonstrate that a *systemic* Type III reaction could occur within a few hours, even in a previously immunized person. *See* Usman at 1, 3 (stating that Type III hypersensitivity reactions typically occur in individuals previously exposed to an antigen; symptoms of serum sickness begin within one to two weeks after the subsequent exposure); Apisarnthanarak at 2-3 (reporting that all patients in the study with serum sickness-like reactions following flu vaccination had developed such reactions following the second dose of vaccine; the median onset of symptoms in such patients was nine days after vaccination, and the minimum time to onset was seven days).

As noted, Petitioner attempts to distinguish "serum sickness" from a "Type III hypersensitivity reaction with systemic inflammation," claiming she suffered the latter, not the former. Reply at 4. She argues that Dr. Tornatore's discussion of "serum sickness" merely provided a "useful framework[]" to understand her condition. *Id*. But Dr. Tornatore failed to explain how a "Type III reaction with systemic inflammation" is medically different from "serum sickness" or a systemic "Type IIIB" reaction, as defined by the Bellanti immunology textbook he supplied. *See* Bellanti at 670-72 (describing "a systemic (serum sickness; Type IIIB) reaction" with no mention of a separate "Type III hypersensitivity reaction with systemic inflammation"). Regardless of what it is called, Dr. MacGinnitie persuasively opined that an immune complex-mediated, systemic reaction would not manifest within hours of a vaccination, as occurred here.[23]

I also find persuasive Dr. MacGinnitie's observation that Petitioner's C3, C4, and CH50 levels were uncharacteristic of a systemic Type III hypersensitivity reaction/serum sickness. MacGinnitie Rep. at 10. This is, again, supported by the Apisarnthanarak paper submitted by Dr. Tornatore, which reported that patients in their study with serum sickness-like disease had decreased C3 and C4 complement levels. Apisarnthanarak at e20. The Usman paper similarly noted that such patients have low C3, C4, and CH50 levels. Usman at 5. Petitioner, by contrast, had normal C3 and C4 levels and elevated CH50 levels. Ex. 29 at 213-14; MacGinnitie Rep. at 11. Notably, Dr. Tornatore did not refute Dr. MacGinnitie's opinion on this point.

2. Intracranial Hypertension

The records show that during Petitioner's initial hospitalization, she underwent an LP that revealed an elevated CSF opening pressure. Ex. 29 at 153. More than nine months later, she was seen by Dr. Kozachuk of the Neuroscience Team. Ex. 25 at 10. Dr. Kozachuk referred her for another LP, which again measured an elevated opening CSF pressure. Ex. 29 at 356. Dr. Kozachuk suspected IH and a laundry list of other conditions. Ex. 25 at 10-11. A third LP given in August 2015 revealed a normal opening pressure. Ex. 11 at 6.

Although Petitioner underwent numerous neurologic and ophthalmologic exams, it is undisputed that she was never diagnosed with papilledema, a clinical sign seen in the large majority of IH cases. *See* Wall at 4. Also, only one treating physician, Dr. Kozachuk, ever observed a VI nerve palsy. Ex. 25 at 10. Troublingly, as discussed above, Dr. Kozachuk's credibility has legitimately been called into question. Petitioner has thus now disavowed reliance on Dr. Kozachuk's assessments. Motion at 5. Furthermore, Dr. Callaghan commented that the Neuroscience Team's care was far different from what a reputable medical practice would provide. First Callaghan Rep. at 6. Dr. Kozachuk assigned multiple diagnoses that did not make sense and/or accord with Petitioner's clinical presentation. *Id.* For these reasons, I discount Dr. Kozachuk's observations and conclusions, including his finding of VI nerve palsy in Petitioner.

[23] Moreover, Petitioner's treating physicians did not suspect or diagnose a "Type III reaction with systemic inflammation"; they assessed "likely serum sickness." Ex. 29 at 139, 150, 159, 173.

The record therefore demonstrates that, although Petitioner had increased CSF opening pressures on two occasions, she did not have papilledema and was not credibly observed to have a VI nerve palsy. The question is whether this is sufficient to support Dr. Tornatore's diagnosis of IH.

Petitioner argues that this diagnosis was appropriate because IH does not require the presence of either papilledema or VI nerve palsy. According to the literature in the record, idiopathic IH can exist without papilledema ("IIHWOP"). *See, e.g.,* Mollan at 2 (recognizing IIHWOP as a separate condition from idiopathic IH). I agree that the absence of papilledema does not by itself rule out an IH diagnosis.

There also is some support in the record for the contention that IIHWOP does not always require the presence of a VI nerve palsy. The 2009 Digre article, for example, reported that only 5% of the IIHWOP patients in their study had a VI nerve palsy. Digre at 187 (Table 2); *see also id.* at 4 (noting that VI nerve palsy was "less common in patients with IIHWOP" than classic IH).[24] However, the 2018 Mollan review paper, which described the consensus views of an interdisciplinary group of clinicians regarding various forms of idiopathic IH, said that while VI nerve palsy is not required to diagnose idiopathic IH with papilledema, it *is* required to diagnose IIHWOP.[25] Mollan at 1089 (Fig. 1). Given its currentness and consensus views, Mollan is a more authoritative source for the diagnostic criteria for IH. Thus, I conclude that because Petitioner had neither papilledema nor a credibly diagnosed VI nerve palsy, IH was not an appropriate diagnosis, even if one of these criteria was not a diagnostic prerequisite.[26]

Finally, looking at the medical records, none of Petitioner's treating physicians, aside from Dr. Kozachuk, ever diagnosed Petitioner with IH. Though the testimony of treating physicians is not sacrosanct, the Federal Circuit has stated that it is "quite probative," and the lack of support for this diagnosis by Petitioner's treating physicians is therefore noteworthy. *See Capizzano*, 440 F.3d at 1326 ("[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause-and-effect show[s] that the vaccination was the reason for the injury.'").[27]

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[24] Petitioner argues that the Wall article likewise stated that VI nerve palsy is only seen in 10-20% of idiopathic IH patients. Motion at 16; *see* Wall at 4. The referenced statement, however, did not address IIHWOP; it discussed the classic form of IIH in which papilledema is present. Wall at 4.

[25] Mollan stated that IIHWOP is "[a] rare subtype of IIH and is seen in patients who meet all the criteria of definite IIH . . . in the absence of papilloedema. The criteria have highlighted the importance of a pressure greater than [twenty-five] cm CSF and the necessity for additional features, which suggest pathologically raised ICP. Features such as sixth nerve palsy and MRI imaging features indicating raised ICP should be sought." Mollan at 1090 (Table 2); *see also id.* at 1089 (Fig. 1) (listing the diagnostic criteria for IIHWOP; VI nerve palsy is a required finding).

[26] Dr. Callaghan also pointed out that Petitioner lacked any of the supportive MRI findings seen in IIHWOP, including "an empty sella, flattening of the posterior aspect of the globe, distention of the perioptic subarachnoid space, or a transverse venous sinus stenosis." First Callaghan Rep. at 6. The Mollan paper makes clear that these findings are important to a diagnosis of IIHWOP. Mollan at 1090 (Table 2).

[27] Additionally, it is notable that Dr. Tornatore saw Petitioner on at least one occasion as a treating physician, several years after her vaccinations. Ex. 42 at 52. At that visit, Dr. Tornatore wrote that

Based on all the evidence before me, therefore, I conclude that Petitioner has failed to preponderantly prove she had IH.[28]

B. Severity

Although Petitioner has failed to establish the threshold requirement of a cognizable injury, I will also address Respondent's contention that Petitioner has not demonstrated she suffered the residual effects of a vaccine-caused injury for more than six months, as required by the Vaccine Act. *See* Response at 25. For even assuming *arguendo* that she did suffer a vaccine-caused, systemic Type III hypersensitivity reaction/serum sickness, she still has the further burden of proving she suffered the residual effects of this injury for more than six months after her vaccination. § 11(c)(1)(D) (requiring a petitioner to prove she suffered the residual effects or complications of her vaccine-caused illness, disability, injury, or condition for more than six months after vaccine administration).

At the outset, it is apparent from the record that Petitioner's initial illness did not *itself* persist for more than six months, even if one assumes it was a systemic, Type IIIB hypersensitivity reaction. As Dr. MacGinnitie persuasively explained, "[s]erum sickness is a self-limited process that resolves over days to weeks." MacGinnitie Rep. at 11. Dr. Tornatore did not refute this point, and it was uniformly supported by the literature in the record, including the articles he supplied. *See* Apisarnthanarak at e21 (reporting the median duration of serum sickness-like symptoms was six days, and the maximum duration was fourteen days; all patients recovered "without further sequelae"); Bellanti at 673 ("Symptoms of serum sickness are usually transient and dissipate within weeks once the offending antigen is removed."); Usman at 7 ("Serum sickness has an excellent prognosis. The symptoms usually resolve 1 to 2 weeks after the withdrawal of the offending agent."); *see also Orgel-Olson v. Sec'y of Health & Human Servs.*, No. 15-285V, 2022 WL 1598143, *29 (Fed. Cl. Spec. Mstr. March 11, 2022) (stating that, if the petitioner "established only that he experienced a serum sickness, he would not be entitled to compensation even if that serum sickness was vaccine-caused," because serum sickness is "a transient condition").

Furthermore, Petitioner's medical records demonstrate that she returned to her baseline only four days after vaccination, except for complaints of headache. Ex. 29 at 135 (Dr. Yang reporting on September 26, 2014, that Petitioner "[was] pretty much back to baseline except for [complaints of headaches]"). Other records from October 13, 2014, November 11, 2014, February 27, 2015, and April 26, 2017, likewise documented that she had "completely recovered" or was

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Petitioner had a history of an "adverse reaction to an influenza vaccination [in] 2014 with subsequent development of a cervical syrinx." *Id.* at 52-53. But Dr. Tornatore did *not* specifically note a history of either a "Type III hypersensitivity reaction" or IH, and he did not diagnose either condition during the visit. He did not assign those diagnoses until this litigation, diminishing the persuasiveness of his opinions.

[28] Dr. Callaghan has opined that Petitioner more likely suffered from a functional neurologic disorder. First Callaghan Rep. at 6. Although there are facts supporting such a conclusion, I need not decide whether this better explains Petitioner's presentation, because I have determined that Petitioner failed to prove the injuries alleged. Furthermore, as Dr. Callaghan rightly pointed out, Petitioner might have had an organic illness concurrently with a functional disorder. Second Callaghan Rep. at 2.

"without symptoms" or "recovered . . . a few days" after vaccination. *See* Ex. 17 at 11 (discussing with her physician on October 13, 2014, that despite some coldness in her right arm, she "otherwise [felt] well."); Ex. 18 at 5-8 (documenting that the physician on April 26, 2017, could find "no evident cognitive defects[.]"); Ex. 22 at 9 (Dr. Capozzoli stating during a February 27, 2015 visit that Petitioner had "completely recovered"); *id.* at 13 (Dr. Capozzoli reporting on November 11, 2014, that Petitioner "had bounced back … rather abruptly and completely and currently [was] without symptoms").

Petitioner contends that her systemic Type III hypersensitivity reaction caused her to develop secondary IH, which endured for at least ten months. Reply at 1-2. As discussed, the record shows that Petitioner had elevated CSF opening pressure readings on two occasions: while hospitalized shortly after vaccination and about ten months later. Ex. 29 at 153, 356. Assuming that Petitioner did develop IH, the question is whether IH is a "residual effect" or "complication" of a systemic Type III reaction which could satisfy the severity requirement.

In *Wright v. Sec'y of Health & Human Servs.*, 22 F.4th 999 (Fed. Cir. 2022), the Federal Circuit addressed the requirements for proving that a particular effect constitutes a "residual effect" or "complication" of a vaccine injury. The Court clarified that, under the Act, "residual effects [are] detrimental conditions within the patient, such as lingering or recurring signs and symptoms." *Id.* at 1005. A "complication" is an event occurring during a disease that is not an essential part of the disease, although it may result from the disease. *Id.* at 1006. The Court held that traditional tort causation principles apply to the determination of whether a particular effect was caused by the vaccine injury. *Id.* at 1005. Thus, to satisfy the severity requirement, a petitioner must prove that "the vaccine injury [was] both a but-for cause of the residual effect and a substantial factor in bringing about the residual effect[.]" *Id.*

Petitioner failed to meet this burden. She did not preponderantly demonstrate that IH can be a "complication" or "residual effect" of a systemic Type III hypersensitivity reaction. As such, she has not proven that her purported vaccine injury – the Type III reaction – was a but-for cause and a substantial factor in inducing her alleged IH.

Dr. Tornatore posited that circulating antigen-antibody complexes produced during a Type III hypersensitivity reaction could cause IH by depositing in the arachnoid granulation vessels, leading to diminished CSF absorption and increased intracranial pressure. First Tornatore Rep. at 18. But the only clinical data he cited on this issue was the Yadav case report, which described the development of IH in a pediatric patient with lupus/SLE. Yadav at 1. In that case, the authors acknowledged that the association of SLE and IH was "unclear." *Id.* at 3. They noted that the "proposed mechanisms include immune-mediated injury within the arachnoid villi and consequent reduction in CSF absorption or probable hypercoagulable state without overt vascular thrombosis giving rise to micro-obliteration of cerebral arteriolar and venous systems." *Id.* They suggested that steroid withdrawal in the treatment of SLE could be a precipitating or predisposing factor in the development of IH in such patients. *Id.* The authors did not propose that circulating immune complexes could decrease CSF absorption through the arachnoid villi/granulations and cause IH, as Dr. Tornatore has opined here. Yadav is therefore distinguishable from the present case, aside from being generally inadequate to demonstrate a potential causal relationship between a Type III hypersensitivity reaction and IH. *See R. V. v. Sec. of Health & Hum. Servs.*, No. 11-504V, 2016

WL 3882519, *41 (Fed. Cl. Spec. Mstr. Feb. 19, 2016) ("individual patient case reports . . . are not[] in general strong evidence of causation" (internal quotation marks omitted)), *mot. for rev. denied,* 127 Fed. Cl. 136 (2016).

Dr. Tornatore also failed to cite any source directly supporting his mechanistic proposition that IH could be caused by a systemic Type III hypersensitivity reaction via decreased CSF absorption through blockage of the arachnoid granulations by immune complexes. Dr. Tornatore relied on the forty-three-year-old Donaldson paper, entitled *Pathogenesis of pseudotumor cerebri syndromes*. *See* Donaldson. In that paper, Dr. Donaldson proposed several different mechanisms for development of IH: increased venous pressure, increased arachnoidal resistance, CSF hypersecretion, and increased elastance of the CSF space. Donaldson at 877-79. He also commented that there is an association between serum sickness and IH, which "cannot yet be classified by etiology." *Id.* at 879. Importantly, Dr. Donaldson did not propose that serum sickness could cause IH through any of the potential mechanisms that he described. *Id.* Instead, he observed that serum sickness causes deposition of immune complexes in the choroid plexus, which is responsible for CSF formation. *Id*. Dr. Donaldson acknowledged that "[h]ow this deposition of immune complexes affects CSF formation is not known."[29] *Id.*

Dr. Callaghan, by contrast, persuasively explained that "the mechanism of [IH] is still unknown today with many potential mechanisms, but not that are definitive." Second Callaghan Rep. at 2. He noted that pathogenic immune complexes, such as those produced in serum sickness, are not one of the currently proposed mechanisms for the development of IH. *Id.* Indeed, the recent literature in the record concerning the etiology of secondary IH did not even discuss serum sickness/Type III reaction as a possible cause of the condition. For example, the 2018 Mollan review paper listed numerous causes of secondary IH; serum sickness/Type III reaction was not included. Mollan at 1092 (Table 3). The 2011 Wall article submitted by Dr. Tornatore also catalogued secondary IH causes – ranging from "highly likely" to "unproven" – and did not identify serum sickness/Type III reaction as even a theoretical cause. Wall at 31-32 (Table 1). Consistent with this, Dr. MacGinnitie observed that the Usman review of Type III hypersensitivity reactions did not identify any residual neurologic complications, including IH. MacGinnitie Rep. at 11; Usman at 8. "[N]or did any of fourteen health care workers with a serum sickness-like reaction after influenza vaccine in the Apisarnthanarak et al report have neurological symptoms." *Id.*; Apisarnthanarak at 4 (reporting that all patients with serum sickness-like illness in their study "recovered without further sequelae.").

In sum, Dr. Tornatore's theory for how a Type III hypersensitivity reaction could cause IH was inadequately substantiated to meet Petitioner's burden of proof. *See Kreizenbeck v. Sec'y of Health & Hum. Servs*., No. 08-209V, 2018 WL 3679843, *31 (Fed. Cl. Spec. Mstr. June 22, 2018)

[29] In her Motion, Petitioner notes that the Donaldson paper stated that meningitis is believed to cause IH by blocking CSF drainage through the arachnoid granulations, which is the mechanism Dr. Tornatore opined applies to Type III reactions/IH. *See* Motion at 24; Donaldson at 878. Importantly, though, blockage of CSF flow through the arachnoid granulations was not the mechanism Dr. Donaldson suggested for development of IH caused by serum sickness. Donaldson at 879. Thus, there was a disconnect between Dr. Tornatore's mechanistic theory and the literature on which the theory was based. *See also* MacGinnitie Rep. at 11.

(when evaluating whether petitioners have carried their burden of proof, special masters consistently reject "conclusory expert statements that are not themselves backed up with reliable scientific support"), *mot. for rev. denied,* 141 Fed. Cl. 138, *aff'd*, 945 F.3d 1362 (Fed. Cir. 2020).

The case of *Song v. Sec'y of Health & Hum. Servs*., 31 Fed. Cl. 61 (1994), is instructive here. The petitioners there alleged that the subject vaccination caused their child to suffer a series of seizures within days of vaccination. *Id.* at 63. Though the seizures resolved, they alleged that this initial injury later caused the child to suffer "residual effects of learning disability, expressive language delay and hypotonia." *Id.* After a hearing, the chief special master concluded that the petitioners had failed to satisfy the severity requirement because they had not shown the child's later delays were a "complication" of his initial post-vaccination injury. *Id.* at 64. The chief special master found that the petitioners' expert relied on unfounded, conclusory statements in attempting to draw this causal connection. *Id.*at 67. The Court of Federal Claims affirmed. *Id.* at 68.

Similarly, in this case Petitioner has failed to preponderantly establish that IH is a potential "residual effect" or "complication" that can be caused by a systemic Type III hypersensitivity reaction. Her claim rests on Dr. Tornatore's unpersuasive conclusion in this regard. Thus, even assuming Petitioner had a vaccine-caused Type III reaction, she has failed to prove that she suffered the "residual effects" of that reaction for the requisite time.

C. *Althen* Prongs

In light of my conclusions that Petitioner failed to prove a cognizable injury and also failed to establish that she suffered the residual effects of any vaccine-caused injury for the requisite period, I need not analyze the *Althen* prongs on the question of whether her flu vaccination caused her to develop a systemic Type III reaction and secondary IH. Nonetheless, for completeness I will address the *Althen* prongs.

As discussed, Petitioner's burden under *Althen*'s first prong is to provide a sound and reliable medical theory causally connecting the vaccination and the injury. *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *Langland v. Sec'y of Health & Hum. Serv.*, 109 Fed. Cl. 421, 441 (2013). Here, Petitioner must preponderantly establish that (1) the flu vaccine can cause a systemic Type III reaction, and (2) that reaction can, in turn, cause the development of secondary IH. For the reasons set forth above, Petitioner did not prove that a systemic Type III reaction can cause IH.[30] Specifically, Dr. Tornatore did not have an adequate basis for his hypothesis that the immune complexes produced during a serum sickness can block the drainage of CSF through the arachnoid granulations, leading to IH. On the other hand, Dr. Callaghan and Dr. MacGinnitie were persuasive in pointing out that serum sickness is not currently

[30] Because I find that Petitioner has failed to meet her burden with respect to the second aspect of causation, I need not address the first.

thought to be a cause of IH, and, conversely, IH has not been observed as a sequela of serum sickness. Thus, *Althen* prong one is not met.

Because Petitioner failed to prove *Althen* prong one, it follows that she cannot prove *Althen* prong two. Still, she failed to preponderantly prove a logical sequence of cause and effect between vaccination and her purported injuries. Under *Althen's* second prong, a petitioner must "prove a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, 418 F.3d at 1278. The sequence of cause and effect must be "'logical' and legally probable, not medically or scientifically certain." *Id.* A petitioner is not required to show "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." *Id.* (internal citations omitted); *Capizzano*, 440 F.3d at 1325. Instead, circumstantial evidence and reliable medical opinions may be sufficient. *Isaac v. Sec'y of Health & Hum. Servs*., No. 08-601V, 2012 WL 3609993, *24 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x 999 (Fed. Cir. 2013). Furthermore, special masters are expected to consider the views of treating doctors on this prong. *Capizzano*, 440 F.3d at 1326. The views of treating doctors can be persuasive because they have direct experience with the patient. *See McCulloch v. Sec'y of Health & Hum. Servs.*, No. 09-293V, 2015 WL 3640610, *20 (Fed. Cl. Spec. Mstr. May 22, 2015).

About two weeks prior to her vaccinations, Petitioner complained of allergy symptoms including rhinorrhea, occasional postnasal drainage, and occasional sinus pressure. Ex. 4 at 2. She was prescribed several medications. *Id.* Within less than twenty-four hours of her vaccinations, she developed fever, malaise, headache, and left arm pain, requiring hospitalization. Ex. 29 at 131-32. Her treating physicians in the hospital mentioned a temporal relationship between her condition and her vaccination status, but none directly attributed the suspected "serum sickness" to her vaccinations. *See id.* at 146, 149. Her symptoms were felt to be psychogenic in nature, but a psychiatric evaluation in the hospital was negative. *Id.* at 153. Her discharge diagnosis was likely serum sickness "after vaccinations." *Id.* at 139.

Petitioner's outpatient neurologist, Dr. Capozzoli, later remarked that she "had a catastrophic reaction possibly to a flu shot three weeks ago." Ex. 22 at 21. He commented that it was "unclear what the etiology of all that was although it seems to have been some sort of severe adverse reaction involving total body weakness." *Id.* Another neurologist, though, diagnosed a functional disorder, characterizing her story as "bizarre." Ex. 18 at 7. There were also several occasions when Petitioner reported her belief that the vaccinations caused her injuries, but her physicians disagreed. *See* Ex. 6 at 10 (ENT Dr. Hilburn commenting that the cause of Petitioner's ear pain was unknown, even though she reported it stemmed from her vaccine reaction); Ex. 4 at 21 (allergist Dr. Gels correcting Petitioner's report that she had GBS caused by her vaccinations). In summary, there was some disagreement among Petitioner's treating physicians as to the cause of her initial presentation. Significantly, though, only Drs. Kozachuk and Newman felt that her purported "secondary IH" was vaccine related. Ex. 25 at 11. Their opinions do not hold weight, for the reasons already discussed.

Ultimately, I am persuaded by Respondent's experts on the question of whether there was a logical connection between Petitioner's vaccinations and her condition. First, as discussed

above, Dr. MacGinnitie provided support for his opinion that the same-day onset of Petitioner's systemic symptoms was too soon to be a vaccine-caused systemic Type III hypersensitivity reaction. MacGinnitie Rep. at 10. Second, as Dr. Callaghan demonstrated, there is no logical explanation in the record connecting Petitioner's initial symptoms to her later ones. On several occasions in the days and months following her post-vaccination hospitalization, physicians noted that Petitioner's symptoms had completely resolved and that she was back to baseline. First Callaghan Rep. at 7. It was not until nine months post-vaccination, and well after her original symptoms dissipated, that she was diagnosed by Dr. Kozachuk with IH. *Id.*

Finally, I need not resolve whether Petitioner's post-vaccination systemic symptoms were caused by a functional disorder and/or an earlier upper respiratory infection, as Dr. Callaghan proposed, because the evidence fails to support the claim that her symptoms were vaccine caused. *Hernandez v. Sec'y of Health & Hum. Servs.*, No. 17-0143V, 2023 WL 9186318, at *2 (Fed. Cl. Spec. Mstr. Dec. 15, 2023) ("Generally, respondent bears the burden of demonstrating the presence of any alternative cause by preponderant evidence only if petitioner satisfies her *prima facie* burden.").

To satisfy *Althen* prong three, a petitioner must establish the "timeframe for which it is medically acceptable to infer causation" and that the onset of her claimed injury occurred within that period. *Shapiro v. Sec'y of Health & Hum. Servs.,* 101 Fed. Cl. 532, 542-43 (2011), *recons. denied after remand on other grounds*, 105 Fed. Cl. 353 (2012), *aff'd without op.,* 503 F. App'x 952 (Fed. Cir. 2013). The record here shows that Petitioner experienced systemic symptoms, including lightheadedness, aches, blurry vision, fever, malaise, weakness, and headache, the same day or the morning after her vaccinations. As discussed, Respondent's expert, Dr. MacGinnitie, citing the literature submitted by Dr. Tornatore, persuasively explained that while a localized/Type IIIA hypersensitivity reaction may occur within four to ten hours after exposure, a systemic/Type IIIB reaction would not occur until several days later. MacGinnitie Rep. at 9-10 (discussing Bellanti). More specifically, four to ten days after exposure to an antigen, soluble immune complexes will be formed and begin to circulate. *Id.* Subsequently, those complexes will deposit in the "blood vessels of the skin, joints, kidneys, and/or lungs," which fixes and activates complement, leading to systemic symptoms such as fever, skin rash, swelling, arthritis, and mild organ damage. *Id.* at 10. Petitioner's course did not fit the timeframe for the development of a vaccine-caused Type IIIB systemic reaction or with the "secondary" development of IH induced by such a reaction. She failed to satisfy *Althen* prong three.

VII. Conclusion

Upon careful evaluation of all the evidence submitted in this matter, including the medical records, affidavit, expert opinions, and medical literature, I conclude that Petitioner has not shown by preponderant evidence that she is entitled to compensation under the Vaccine Act. **Her petition is therefore DISMISSED. The clerk shall enter judgment accordingly.**[31]

IT IS SO ORDERED.

[31] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing (either jointly or separately) a notice renouncing their right to seek review.

s/ Jennifer A. Shah
Jennifer A. Shah
Special Master